

Exhibit 5

Daniel Fabricant, Ph.D.
IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

UNDETERMINED QUANTITIES OF
1,3-DIMETHYLAMYLAMINE
HCl (DMAA),

Defendant,

and

HI-TECH PHARMACEUTICALS,
INC., and JARED WHEAT,

Claimants.

Civil Action No.

1:13-cv-13675-

WBH-JCF

Deposition of Daniel Fabricant, Ph.D.
Washington, D.C.
Monday, November 21, 2016
9:30 a.m.

Job No. 115859

Reported by: Laurie Donovan, RPR, CRR

Daniel Fabricant, Ph.D.
 Deposition of
 DANIEL FABRICANT, Ph.D.

Held at the offices of:
 United States Department of Justice
 Consumer Protection Branch
 450 5th Street, N.W.
 Washington, D.C. 20001

Taken pursuant to notice, before
 Laurie Donovan, Registered Professional
 Reporter, Certified Realtime Reporter, and
 Notary public in and for the District of
 Columbia.

Daniel Fabricant, Ph.D.
 A P P E A R A N C E S
 ON BEHALF OF THE PLAINTIFF:
 United States Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, Maryland 20993
 By: Joshua Davenport, Esq.

- and -

United States Department of Justice
 450 5th Street, N.W.
 Washington, D.C. 20530
 By: Claude Scott, Esq.

ON BEHALF OF THE DEFENDANTS:
 Epstein Becker & Green
 One Gateway Center
 Newark, New Jersey 07102
 By: Jack Wenik, Esq.

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 25

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1 Daniel Fabricant, Ph.D.
 2 mispronounce it, feel free to correct me.
 3 Other than that, do you have any
 4 questions for me before we begin?
 5 A No.
 6 (Exhibit 1 was marked for
 7 identification.)
 8 BY MR. SCOTT:
 9 Q So, Doctor, I've placed before you what
 10 I've marked as Fabricant Exhibit 1, the subpoena
 11 for testimony in this case, and you are appearing
 12 pursuant to the subpoena in this matter?
 13 A Yes.
 14 Q All right. Is the government
 15 representing you for purposes of these
 16 proceedings?
 17 A Yes.
 18 Q Do you have your own counsel involved in
 19 this, or just you're relying on the government?
 20 A Right now just relying on the
 21 government.
 22 Q Okay. That may be a mistake, but that's
 23 okay.
 24 So the government lawyers can interpose
 25 objections when they want to, when they feel

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1 Daniel Fabricant, Ph.D.
 2 P R O C E E D I N G S
 3 DANIEL FABRICANT, Ph.D.,
 4 having been first duly sworn, testified upon
 5 his oath as follows:
 6 EXAMINATION BY COUNSEL FOR DEFENDANT
 7 BY MR. WENIK:
 8 Q Good morning, Dr. Fabricant, and thank
 9 you for coming.
 10 Have you been deposed before?
 11 A Yes.
 12 Q So I assume you're somewhat familiar
 13 with the procedure, but for the benefit of the
 14 record, I'll put a couple of things before you.
 15 One is that your testimony is being
 16 taken under oath, so we need an oral response for
 17 the stenographer, not a nod of the head or a
 18 gesture.
 19 The other thing is if I ask you a
 20 question and you didn't hear it, didn't understand
 21 it, you know, please speak up, ask me to rephrase
 22 or repeat it. Otherwise, I'll assume you've
 23 understood the question and heard it.
 24 And if I use a term, particularly a
 25 medical or scientific term, improperly or

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1 Daniel Fabricant, Ph.D.
 2 something is inappropriate, but other than an
 3 instruction not to answer a question because of
 4 some privilege, you should put an answer on the
 5 record. Okay?
 6 So just a couple of housekeeping things.
 7 Could you state and spell your full name for the
 8 record?
 9 A Daniel Stuart Fabricant, D-A-N-I-E-L,
 10 S-T-U-A-R-T, F-A-B-R-I-C-A-N-T.
 11 Q And what is your business address,
 12 Doctor?
 13 A 440 First Street, Washington, D.C.
 14 Q And your home address?
 15 A 4307 Chesapeake Street, D.C.
 16 Q For purposes of today's deposition, what
 17 did you do to prepare, other than any confidential
 18 attorney/client privileged conversation? Did you
 19 review any documents? Did you have any
 20 discussions with anyone?
 21 A Just discussion with the government
 22 attorneys.
 23 Q Okay.
 24 Let me ask you a little bit about your
 25 background, because I don't have the benefit of

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1 Daniel Fabricant, Ph.D.
 2 your CV.
 3 First of all, have you ever testified --
 4 let me rephrase that.
 5 Have you ever been retained as an expert
 6 witness in a litigation?
 7 A Yes.
 8 Q All right. In what sort of subject
 9 matters have you been retained as an expert?
 10 A Regulatory status, chemistry,
 11 toxicology, foods and dietary supplements.
 12 Q And have those matters been where you've
 13 been retained by the government or private
 14 industry?
 15 A Private industry.
 16 Q Okay, and how often have you been
 17 retained as an expert?
 18 A Three cases.
 19 Q And do you remember the names of those
 20 cases?
 21 A Yes. Two are under seal, but it's --
 22 they're both against Monster Energy, and one was a
 23 company called Happy versus Procter & Gamble.
 24 Q And what sort of matters were these?
 25 Were these patent cases, intellectual property

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1 Daniel Fabricant, Ph.D.
 2 A Senate Judiciary was on dietary
 3 supplements, anabolic steroids, and 2014 was on
 4 claims, dietary supplement claims, and the Federal
 5 Trade Commission.
 6 Q And in those two matters -- well, let's
 7 take the 2009 first. I'm not going to do a
 8 compound question.
 9 So were you testifying as a
 10 representative of the Natural Products Association
 11 in 2009?
 12 A Yes, I was.
 13 Q And in the 2014 matter, was that --
 14 A Same. Natural Products Association.
 15 Q Okay.
 16 Have you ever been convicted of a crime?
 17 A Traffic offenses.
 18 Q I'm not interested in those.
 19 Have you ever been a party to a
 20 litigation as a plaintiff or defendant? And let
 21 me add I'm not interested in your divorce or an
 22 auto accident. I mean in your professional
 23 capacity.
 24 A Yes.
 25 Q And tell me about those.

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1 Daniel Fabricant, Ph.D.
 2 cases?
 3 A No. Regulatory, dealing with regulatory
 4 status of ingredients, safety/toxicology of
 5 ingredients, FDA Food, Drug and Cosmetic Act law.
 6 Q All right. Have you ever testified in a
 7 court of law as an expert as opposed to a
 8 deposition?
 9 A Only my divorce hearing.
 10 Q I don't need to go into that.
 11 I take it in those three matters you
 12 prepared expert reports of some sort?
 13 A I did.
 14 Q Okay. Other than the divorce matter
 15 which I'm not interested in, have you ever
 16 testified in a public trial or arbitration or
 17 hearing of any sort?
 18 A No.
 19 Q Have you ever --
 20 A Well, actually, two Senate hearings
 21 would count, I guess, under that, in front of
 22 Senate Judiciary in 2009, in front of Senate
 23 Commerce in 2014.
 24 Q Okay. What was the subject matter of
 25 what you testified?

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1 Daniel Fabricant, Ph.D.
 2 A Well, when I was at FDA, there were
 3 obviously a number of cases that were brought
 4 against the government, some for regulatory and
 5 final agency action, and then there's been some
 6 suits at NPA, mostly labor type stuff.
 7 Q EEOC type complaints, discrimination
 8 type things?
 9 A Yes, mostly EEOC or wrongful
 10 termination, those kinds of things.
 11 Q All right. Let me ask you a little bit
 12 about your education.
 13 My understanding is that you have a
 14 degree in chemistry from the University of North
 15 Carolina; is that right?
 16 A My undergraduate degree, yes.
 17 Q When did you get that?
 18 A 1997.
 19 Q And was there a particular area of
 20 chemistry that you majored in? Was it organic or
 21 some other type or just chemistry in general?
 22 A I had a specialty in organic. I took
 23 extra course work in organic.
 24 Q And I also understand that you have a
 25 Ph.D. in pharmacognosy; is that right?

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1 Daniel Fabricant, Ph.D.
 2 A That's correct.
 3 Q And is that from the University of
 4 Illinois Chicago?
 5 A Yes.
 6 Q When did you get that?
 7 A 2005.
 8 Q Any other graduate degrees or other
 9 higher education?
 10 A The government sent us to Harvard
 11 Kennedy School for the Strategic Management of
 12 Regulatory and Enforcement Agencies. We did that
 13 in 2012.
 14 Q I suppose I should ask, even though I
 15 know what it means, but to flesh out the record,
 16 what is pharmacognosy?
 17 A It's the study of natural products.
 18 It's development of medicines from generally
 19 plants.
 20 Q And were you involved in, when you were
 21 having your course work in the Ph.D., in research
 22 into botanicals?
 23 A Yes.
 24 Q And was that as part of the Botanical
 25 Research Center at the University of Illinois?

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1 Daniel Fabricant, Ph.D.
 2 you've published?
 3 A Everything from botanical dietary
 4 supplements to drug discovery to regulatory status
 5 to toxicology, so a pretty wide range.
 6 Q Okay. Have you published anything
 7 regarding DMAA?
 8 A Yes.
 9 Q What sorts of articles have you
 10 published?
 11 A There's a book chapter in "Regulatory
 12 Toxicology" which touches on DMAA.
 13 Q I'm sorry. The name of that book -- is
 14 that a textbook or --
 15 A Yes, it's a textbook.
 16 Q And what's the title of that textbook?
 17 A "Regulatory Toxicology."
 18 Q All right.
 19 Do you hold any patents?
 20 A No. Well, the Association does under my
 21 signature, but me personally, no.
 22 Q Okay. What sorts of patents does the
 23 NPA hold that you were involved with?
 24 A Trademarks. If you look on lip balms,
 25 we came up with a term to qualify what "natural"

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1 Daniel Fabricant, Ph.D.
 2 A Yes.
 3 Q And did you work with Dr. Van Breeman?
 4 A He wasn't my advisor, but he was on my
 5 defense committee, my dissertation defense
 6 committee.
 7 Q Okay. What is your view of the academic
 8 reputation of Dr. Van Breeman?
 9 A Very good.
 10 Q Have any questions about his integrity?
 11 A No reason to.
 12 Q His scientific knowledge?
 13 A No reason to.
 14 Q And what was the subject of your
 15 dissertation?
 16 A Black cohosh. It's a plant that grows
 17 in the Appalachians. It's used for menopause.
 18 Q Have you published any articles or
 19 research in peer-reviewed literature?
 20 A Yes.
 21 Q Approximately how many articles have you
 22 published?
 23 A About 20.
 24 Q And what are the, generally, the subject
 25 areas of interest to you in your research that

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1 Daniel Fabricant, Ph.D.
 2 is in the marketplace, so if you look at "natural
 3 personal care," we patented that, that mark.
 4 Q Okay, and this book chapter that you
 5 were involved with in the "Regulatory Toxicology,"
 6 do you remember roughly what year that may have
 7 come out or was public?
 8 A It came out in 2015.
 9 Q Okay.
 10 So have you actually conducted research?
 11 And when I say "research," I don't mean reading
 12 like scientific literature, but I mean
 13 experimentation regarding DMAA either in animals,
 14 in humans, in vitro, in vivo.
 15 Any original research that you
 16 personally conducted regarding DMAA?
 17 A Do you mean that -- just so I'm clear,
 18 do you mean did I inject animals with DMAA?
 19 Q Right. In other words, you know, I
 20 understand you must have done some research to
 21 publish this chapter in the sense of research and
 22 reading things, but I'm saying conducting an
 23 experiment of some sort, either in animals, in
 24 humans or what-have-you.
 25 A No.

Page 22	Page 23
<p>1 Daniel Fabricant, Ph.D. 2 Q Let me ask you a little bit about some 3 of your prior positions. I understand that you 4 worked for Consumer Labs at one point? 5 A Yes. 6 Q What was your position with Consumer 7 Labs? 8 A I was the assistant director for 9 research. 10 Q And when was that? 11 A 2005. 12 Q And what were your duties as assistant 13 director for research? 14 A Coordinated testing, both in the US and 15 Japan, of a variety of consumer health products, 16 primarily dietary supplements, and interpreted the 17 research results for publication. That's kind 18 of -- that was the base of it. Obviously there 19 were a lot of other things involved, but that was 20 largely the base of it. 21 And I also was the spokesperson 22 sometimes for the organization, and I evaluated 23 lab capabilities in terms of which labs were doing 24 things the right way and which labs weren't. 25 Q So did Consumer Labs actually bring</p>	<p>1 Daniel Fabricant, Ph.D. 2 products to market? 3 A No. 4 Q Would it do it on behalf of other 5 companies? 6 A Consumer Lab was a -- they did 7 independent testing of products that were already 8 available for purchase at the consumer level. 9 Q I see, and how long did you hold this 10 position with Consumer Labs? 11 A For 11 months. 12 Q And I understand that you've had a 13 couple of different stints with the Natural 14 Products Association; is that right? 15 A Two. 16 Q Tell me about the first one. What was 17 your positions and when was it and what did you 18 do? 19 A First I was hired in January of 2006 to 20 be the vice president of science and regulatory 21 affairs. 22 Q So would that have been right after you 23 completed your Ph.D. that you began that position? 24 A Well, when I was at Consumer Lab, I had 25 finished my Ph.D. I just needed to defend it,</p>
Page 24	Page 25
<p>1 Daniel Fabricant, Ph.D. 2 so . . . 3 Q So it would be your Ph.D., Consumer 4 Labs, then NPA; is that right? 5 A Yes. 6 Q Okay. So that first position, you were 7 vice president of scientific affairs? Is that 8 what you said? 9 A Scientific and regulatory. 10 Q And how long did you do that for? 11 A These years, three and a half years 12 until I became interim CEO. 13 Q Okay, and what were your duties as the 14 vice president of scientific affairs? 15 A Well, I was the organization's lead on 16 all things scientific on interaction with 17 scientific bodies, federal agencies, both domestic 18 and abroad. Corralled the association members on 19 different scientific positions. I wrote all the 20 association's positions and comments on regulatory 21 and scientific matters, as well as a spokesperson 22 for the organization. 23 Q All right, and what did you do as the 24 interim CEO? 25 A Ran the company, made sure that, you</p>	<p>1 Daniel Fabricant, Ph.D. 2 know, we had, we had everything in the right 3 place. Assumed the role of the chief of all 4 advocacy functions, both domestic and abroad. We 5 had a number of contracts as well, both with NIH 6 and with Department of Commerce. 7 So it was pretty extensive, my role as 8 CEO in that short period of time, but we got a lot 9 done, it's about a three and a half million 10 dollars organization. At that time we had 16 11 full-time staff, so obviously in charge of 12 financially making sure that we were doing the 13 right things. 14 Q What individuals or entities forms the 15 bulk of the membership of the NPA, what sorts of 16 entities or members of the Natural Products 17 Association? 18 A It's split between manufacturers and 19 retailers of natural health foods, natural 20 products. 21 Q All right. Let's put the FDA aside for 22 a moment. 23 A Okay. 24 Q So you're currently the CEO of the 25 Natural Products Association; is that right?</p>

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1 Daniel Fabricant, Ph.D.
 2 A I am.
 3 Q And are the duties that you have now
 4 similar to what you described or the same as when
 5 you were the interim CEO?
 6 A No. There's a lot more going on, so
 7 they're enhanced.
 8 Q All right. How are they enhanced?
 9 A It's just very active. I think we're
 10 much more active congressionally, much more active
 11 in that regard.
 12 Q All right. So were there any other
 13 positions that we've not discussed that you've
 14 held? We talked about Consumer Labs, we talked
 15 about NPA, and we're going to talk about the FDA
 16 in a little bit. Anything other than that that
 17 you've done occupation-wise?
 18 A Well, I was employed by the University
 19 of Illinois when I was a graduate student. I was
 20 a research assistant. I had fellowships from NIH
 21 there, so -- and then I also worked for Viragen
 22 Pharmaceuticals. They were based in south
 23 Florida. They no longer function. I was an R&D
 24 chemist there and made interferon from human white
 25 blood cells instead of recombinant.

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1 Daniel Fabricant, Ph.D.
 2 confidential was by the government.
 3 MR. SCOTT: Okay, and that's fine.
 4 I think there's a provision in the protective
 5 order that gives us some period of time to do
 6 that. We'll just deal with it then.
 7 MR. WENIK: That's what I would
 8 suggest. Rather than interrupt the
 9 deposition as it's going on, after you get
 10 the transcript, you can go through the
 11 errata, submit whatever designations you'd
 12 like.
 13 BY MR. WENIK:
 14 Q So let me again get to why you're here
 15 is your position with the FDA. My understanding
 16 is that you were at the FDA from February of 2011
 17 to April of 2014.
 18 Does that sound about right?
 19 A Yes.
 20 Q And did you hold different positions
 21 during that time span, or did you hold the same
 22 position?
 23 A The same.
 24 Q And what was that position?
 25 A Director of the Division of Dietary

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1 Daniel Fabricant, Ph.D.
 2 Q I see, and when did you do that?
 3 A In 1997.
 4 MR. WENIK: All right. So let me
 5 discuss for a moment before I begin talking
 6 about the FDA -- so gentlemen, I'm going to
 7 be showing Dr. Fabricant certain documents
 8 that are subject to the protective order, so
 9 rather than stop at each point in the
 10 deposition, what I propose is we just go
 11 through it, and after it's transcribed, you
 12 can designate whatever portions of the
 13 transcript you'd like as confidential or
 14 subject to the protective order rather than
 15 interrupt and put that on the record for each
 16 document.
 17 MR. SCOTT: Are these documents
 18 that the government designated as
 19 confidential?
 20 MR. WENIK: Correct.
 21 MR. SCOTT: Well, that process is
 22 fine for those. Are there any that third
 23 parties have designated?
 24 MR. WENIK: Not that I know of.
 25 What I'll be showing him that's designated as

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1 Daniel Fabricant, Ph.D.
 2 Supplement Programs.
 3 Q Okay, and what were your duties in that
 4 position?
 5 A I was the agency's lead in all things
 6 dietary supplements. Reported to upper management
 7 on regulatory, legal, budgetary aspects. Really
 8 made sure the program was vital in terms of, as
 9 it's one of the core functions of FDA, at least on
 10 the food center, one of the -- you know, involved
 11 in food safety, also food additive safety, et
 12 cetera. Dietary supplements were under the Office
 13 of Nutrition, Labeling, and Dietary Supplements.
 14 Q And approximately how many people did
 15 you supervise in your division?
 16 A I had 26 FTEs.
 17 Q Let me show you a document that has been
 18 previously marked as Keefe Exhibit 4. We'll mark
 19 it as Fabricant Exhibit 2.
 20 (Exhibit 2 was marked for
 21 identification.)
 22 BY MR. WENIK:
 23 Q Dr. Fabricant, I've placed before you a
 24 document that I've marked for identification as
 25 Fabricant Exhibit 2, which, for the record, is an

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1 Daniel Fabricant, Ph.D.
 2 organizational chart of the FDA in 2013.
 3 Have you seen this before, by the way?
 4 A Mm-hmm, yes.
 5 Q Okay. So does this accurately reflect
 6 the organization of the FDA in 2013, as far as you
 7 can tell?
 8 A Yes.
 9 Q All right. I'm looking down at the
 10 bottom right corner where it says "Office of
 11 Nutrition, Labeling, and Dietary Supplements."
 12 Is that the branch or subdivision, if
 13 you will, of the FDA that you were a part of?
 14 A The office.
 15 Q Okay, and Philip Spiller, who is listed
 16 here, what was his role?
 17 A Well, he was the acting director after
 18 Barbara Schneeman retired.
 19 Q Did you report to Mr. Spiller?
 20 A I did.
 21 Q And who would he report to?
 22 A The center director, specifically --
 23 well, they switched between the deputy directors,
 24 but largely the center directors. Sometimes we
 25 would report to Roberta Wagner, and sometimes we

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1 Daniel Fabricant, Ph.D.
 2 A He did. He also served as an expert for
 3 the FDA.
 4 Q And Mr. Hilmas, did he join you at the
 5 NPA after you left the FDA?
 6 A Dr. Hilmas.
 7 Q Dr. Hilmas, yes.
 8 A Yes.
 9 Q Did you know him before your stint with
 10 the FDA?
 11 A No.
 12 Q Jennifer Thomas; is that a name that's
 13 familiar to you from the FDA?
 14 A Yes.
 15 Q Who is she?
 16 A She worked in the Office of Compliance
 17 at my time at the FDA.
 18 Q All right, and that would be two boxes
 19 over here on the left?
 20 A Yes.
 21 Q All right, and what was her role at the
 22 FDA?
 23 A She was the director of the Division of
 24 Enforcement at the Office of Compliance.
 25 Q Now, when you were in the director

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1 Daniel Fabricant, Ph.D.
 2 would report to Steve Musser.
 3 Q And where would you be in the chain of
 4 command here? Were you like the number two person
 5 under Mr. Spiller in the Office of Nutrition,
 6 Labeling, and Dietary Supplements, or how would
 7 you characterize it?
 8 A Each office has divisions under this
 9 office, so I was one of the division directors
 10 under the office.
 11 Q I see. So you would be the division
 12 director of dietary supplements?
 13 A Correct.
 14 Q Corey Hilmas; is that somebody that's
 15 familiar to you?
 16 A Yes.
 17 Q And was he with the FDA during your
 18 tenure there?
 19 A Yes.
 20 Q What was his position?
 21 A He was originally a tox reviewer for the
 22 New Dietary Ingredient Notification Team, and then
 23 he was the head of the regulations and
 24 implementation branch.
 25 Q And did he report to you?

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1 Daniel Fabricant, Ph.D.
 2 position of dietary supplements at the FDA, was
 3 one of your duties to take action against dietary
 4 supplements that you felt posed a hazard?
 5 A Yes. Well, to clarify, it's not that we
 6 felt had a hazard; it was that we had evidence of
 7 a violation of the Food, Drug and Cosmetic Act.
 8 Q And would you prioritize those
 9 substances that you thought or that the FDA
 10 believed posed a health hazard as opposed to some
 11 other violation?
 12 MR. SCOTT: Object as to form.
 13 THE WITNESS: We don't prioritize
 14 based on feeling; we base it on the evidence
 15 that we have.
 16 BY MR. WENIK:
 17 Q So if you had evidence that something
 18 posed a health hazard, would that be a priority as
 19 opposed to some other violation of an FDA
 20 regulation?
 21 A With the Food, Drug & Cosmetic Act, any
 22 violation intimates a health hazard. It's mens
 23 rea, so you don't -- it doesn't necessarily -- if
 24 it's misbranded or adulterated, it's already, by
 25 law, deemed a health hazard.

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1 Daniel Fabricant, Ph.D.
 2 Q Well, I guess let me put it this way:
 3 How would you prioritize when you were at FDA?
 4 Obviously, I can't expect you to testify to what's
 5 happening today, but when you were at FDA in that
 6 2011 to 2014 block, how would you prioritize what
 7 violations to take action against? I assume there
 8 are more violations that occurred than you had
 9 resources to address; is that fair?
 10 MR. SCOTT: Objection as to form.
 11 Objection; compound. That's two questions.
 12 BY MR. WENIK:
 13 Q Let me rephrase. That's a fair
 14 objection.
 15 Would it be fair to say that during your
 16 tenure, your office became more violations of the
 17 Food, Drug & Cosmetic Act than you had resources
 18 to address?
 19 MR. SCOTT: Object as to form.
 20 THE WITNESS: We addressed anything
 21 that came up to us that we were knowledgeable
 22 about. That was the role of my office. We
 23 were the expert office, so when a case came
 24 in, either from the districts or something
 25 that we developed ourselves, we were

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1 Daniel Fabricant, Ph.D.
 2 it case by case. I stand on my track record
 3 that we acted appropriately in all of our
 4 actions.
 5 BY MR. WENIK:
 6 Q All right.
 7 Are you familiar with an individual at
 8 the FDA during your time period named Robert
 9 Moore?
 10 A Dr. Moore, yes.
 11 Q What is your recollection of what
 12 Dr. Moore's position was at the FDA?
 13 A Dr. Moore was the lead for the
 14 regulations implementation team at the time, and
 15 he was there for eight months with me, and then he
 16 retired.
 17 Q And he reported to you?
 18 A Yes.
 19 Q Was he someone that performed
 20 satisfactorily, in your view?
 21 A Yes.
 22 Q And what were his duties?
 23 A He managed largely the interactions with
 24 the Office of Compliance, with the attorneys, and
 25 with a lot of stakeholders when I arrived. His

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1 Daniel Fabricant, Ph.D.
 2 obligated to act, so I think -- you know, I
 3 don't -- I'm not sure of your question, I
 4 guess. I don't understand what it is you're
 5 trying to get to.
 6 BY MR. WENIK:
 7 Q Well, would you devote more resources to
 8 certain violations than others?
 9 A It's on a case by case. You know, we
 10 took it case by case. It really depends on --
 11 there's a process and the preponderance of the
 12 evidence, and we try to take it -- again, I think
 13 in dispatching our duties we did that. We really
 14 looked at a case-by-case scenario. Where a case
 15 required more resources, it was generally given
 16 more resources. Where a case may not have
 17 required more resources, it wasn't, but again it's
 18 always case by case.
 19 Q And would you devote more resources to a
 20 case that your branch, if you will, your division
 21 felt posed a greater health risk to the public
 22 than others that posed less of a health risk?
 23 MR. SCOTT: Object as to form.
 24 THE WITNESS: Again, you're asking
 25 me to speculate. I'm not having -- we took

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1 Daniel Fabricant, Ph.D.
 2 duties, because he was retiring, diminished, and
 3 he largely was focused on helping Dr. Hilmas
 4 manage that position in that branch, and
 5 Dr. Hilmas really applied his vision to what that
 6 branch should be.
 7 Q What was his area of expertise?
 8 A He had a degree in biochemistry.
 9 Q Was he someone whose judgment you
 10 trusted?
 11 A Bob, most of the time, yeah, he did a
 12 very good job most of the time. There was
 13 always -- I mean you always have a review of
 14 things, and one of the challenges when I arrived
 15 at the organization, and of no fault of Bob's, but
 16 there wasn't a lot of -- there wasn't a robust
 17 enforcement program or regulatory program in terms
 18 of dietary supplements when I arrived, and so that
 19 was largely what I was hired for was to try to,
 20 you know, get all of the functions operating.
 21 Q To increase the robustness of it, for
 22 lack of a better word?
 23 A To set up systems that increased the
 24 robustness of it, yes, to make it to where all
 25 parts of the law were being, you know, adequately

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1 Daniel Fabricant, Ph.D.
 2 taken care of.
 3 Q All right. Did you respect Dr. Moore's
 4 scientific judgment?
 5 MR. SCOTT: Object as to form.
 6 THE WITNESS: Is there a specific
 7 matter?
 8 BY MR. WENIK:
 9 Q Well, just generally, is he someone that
 10 you felt was competent and knowledgeable?
 11 A In general, yes, and again, through no
 12 fault of his own, there was a culture of somewhat
 13 inactivity before my arrival, so we, you know,
 14 that was -- and he was retiring as well, so
 15 sometimes I think that he may have factored into
 16 some decision-making.
 17 Q All right. Did you seek him out for
 18 advice regarding DMAA?
 19 MR. SCOTT: Object as to form.
 20 THE WITNESS: I sought out a lot of
 21 people for advice on DMAA. I sought out the
 22 whole division for advice on really the NDI
 23 provision and setting up a system to be more
 24 effective to the letter of the law.
 25

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1 Daniel Fabricant, Ph.D.
 2 A I've been in a bioequivalence trial back
 3 when I was a graduate student.
 4 Q And you mentioned that you've done some
 5 animal study work?
 6 A Yes.
 7 Q When did you do that?
 8 A Both at NPA prior, and then my time at
 9 FDA, there were a few animal studies while I was
 10 at FDA and NPA that were published.
 11 Q Have you ever served as a peer reviewer
 12 for a journal?
 13 A Yes.
 14 Q What journal have you served as a peer
 15 reviewer for?
 16 A A number of them. I can't recall all of
 17 them offhand. I can provide my CV. They have
 18 them all listed there, but it's somewhere in the
 19 neighborhood of eight to ten journals. I can't
 20 recall the exact number at this time, but a
 21 number.
 22 Q How long have you been doing that,
 23 serving as a peer reviewer?
 24 A Since graduate school, so ten plus
 25 years.

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q And was he one of the people that you
 4 may have reached out to?
 5 A The whole division. I reached out to
 6 the whole division.
 7 Q Okay. Let me talk a little bit more
 8 about your expertise.
 9 Have you ever designed a human clinical
 10 trial?
 11 A Yes.
 12 Q How often have you done that?
 13 A Probably, over the past two some years,
 14 probably about five or six trials.
 15 Q And that's with the NPA?
 16 A At NPA we have some members who have
 17 contract research organizations, and so we -- at
 18 times we'll advise them through either formal
 19 committees or through meetings.
 20 Q Prior to the past two years you
 21 described, have you ever done that before,
 22 designed a human clinical trial?
 23 A No. Animal studies.
 24 Q Have you ever served as an investigator
 25 in a human clinical trial?

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1 Daniel Fabricant, Ph.D.
 2 Q What subject areas are these journals?
 3 Are these natural products journals or chemistry
 4 journals?
 5 A Chemistry, natural products, regulatory,
 6 legal, a variety, a wide variety.
 7 Q And as a peer reviewer, have you
 8 received manuscripts of research for your review?
 9 A Yes.
 10 Q Have you commented on that?
 11 A Yes.
 12 Q So let's talk a little bit then about
 13 the scientific method. What is your understanding
 14 of a case report, what a case report is?
 15 MR. SCOTT: Object as to form.
 16 THE WITNESS: Do you mean a case
 17 report in the literature that talks about
 18 some sort of health condition for one
 19 specific patient?
 20 BY MR. WENIK:
 21 Q Correct.
 22 A Yes, I'm familiar with those.
 23 Q All right, and is it as you described,
 24 it reports a medical event of some sort for an
 25 individual or individuals?

1 Daniel Fabricant, Ph.D.
 2 A Usually, yes.
 3 Q In your mind, is a case report
 4 sufficient evidence to establish causation between
 5 a substance and a medical condition?
 6 A They can be, depending on the quality of
 7 the case report.
 8 Q Just the case report alone?
 9 A If it's a good enough case report and
 10 there is underlying evidence, it could.
 11 Q And what sort of underlying evidence
 12 would you look for?
 13 A Medical history, challenge, dechallenge.
 14 Dechallenge is when you give an agent and then you
 15 take it away, and the symptoms recur. Those are
 16 generally some large confounders, but it would
 17 have to be on a case-by-case basis to establish
 18 what would make that case report stronger versus
 19 others, but those are some of the things you look
 20 for typically is -- the medical history is
 21 incredibly important.
 22 Q Are you familiar with the Bradford Hill
 23 criteria for causation?
 24 A Somewhat, but I'm not -- I need a
 25 refresher.

1 Daniel Fabricant, Ph.D.
 2 Q That Bradford Hill criteria, is that
 3 something you used or applied when you were at the
 4 FDA?
 5 A No. Our officers used something called
 6 CIOMS by the World Health Organization.
 7 Q And what's your understanding of what
 8 CIOMS is?
 9 A CIOMS is at least globally recognized as
 10 the best way to evaluate an adverse event report
 11 or adverse event reports, and it gives a way to
 12 score and rank those adverse event reports and
 13 assign if it's possible, probable, there's a
 14 temporal relationship, if it's incomplete, if more
 15 information is need, if it's unlikely, and there's
 16 a lot that goes into evaluating those.
 17 Q Would you prepare those, or other people
 18 at FDA would prepare those for you, those
 19 analyses?
 20 MR. SCOTT: Object as to form.
 21 BY MR. WENIK:
 22 Q Let me repeat the question.
 23 Those CIOMS analyses that you described,
 24 did you personally prepare those, or did others at
 25 FDA prepare those for you?

1 Daniel Fabricant, Ph.D.
 2 MR. SCOTT: Object as to form.
 3 THE WITNESS: The medical officers
 4 prepared those.
 5 BY MR. WENIK:
 6 Q Let's return to peer reviewing for a
 7 moment. What is your understanding of what the
 8 function of peer review is?
 9 A To make sure that there is appropriate
 10 scientific rigor.
 11 Q Now, when something is published in a
 12 scientific journal, in your view, is it important
 13 that the information that's published be accurate?
 14 A Yes.
 15 Q Would that be something you'd be looking
 16 for as a peer reviewer?
 17 A Yes.
 18 Q Do most scientific studies begin with
 19 the researcher having a hypothesis of some sort?
 20 A A hypothesis-driven research, yes.
 21 Q And is the goal of scientific research,
 22 when one has a hypothesis, to either prove or
 23 disprove the hypothesis?
 24 A Not necessarily.
 25 Q And what else would be the goal?

1 Daniel Fabricant, Ph.D.
 2 A Well, sometimes you publish research
 3 that you have different findings. Serendipity
 4 comes into play as well, so it's not always
 5 that -- you know, you may venture down an avenue
 6 with a certain hypothesis and find out other
 7 things.
 8 Q As a peer reviewer and as a scientist --
 9 let me back up.
 10 Do you consider yourself a scientist?
 11 A Yes.
 12 Q As a peer reviewer and as a scientist,
 13 do you believe it's appropriate for researchers to
 14 determine the conclusion of their research before
 15 they conduct the research itself?
 16 A No.
 17 Q Not appropriate?
 18 A Well, that's why you have a hypothesis.
 19 You test it.
 20 Q Is one of the things that you're looking
 21 for as a peer reviewer to see whether the
 22 researchers are biased?
 23 MR. SCOTT: Object as to form.
 24 THE WITNESS: Even if there is
 25 bias, that's the role of the peer review

1 Daniel Fabricant, Ph.D.
2 process is to help to remove the bias. Even
3 if there is, I mean I think that researchers
4 tend to like the area they're focused on, and
5 so you can't inherently remove all bias, but
6 the point of peer review and why it's so
7 important is to effectively have some
8 scientific guardrails against bias clouding
9 the actual results.

10 BY MR. WENIK:

11 Q When you're doing your peer review as a
12 journal peer reviewer -- and you mentioned I
13 believe you do it for a number of different
14 journals -- is one of the things that you're
15 looking at the funding of the research that's been
16 submitted?

17 A It factors in, yeah. They have to
18 disclose that.

19 Q And how does that factor into your
20 analysis or review of the research?

21 A Well, it leads you to -- oftentimes in
22 peer review you'll look at other references that
23 are related, so it prompts you to look at either a
24 body of work or a history of work or a focus of
25 work.

1 Daniel Fabricant, Ph.D.
2 case by case.

3 Q Is it inappropriate for the sponsor of
4 research to have a role in which methodologies are
5 employed in conducting the research?

6 MR. SCOTT: Object as to form.

7 THE WITNESS: It can. It certainly
8 can. Again, it's case by case.

9 BY MR. WENIK:

10 Q So some cases yes, some no?

11 A Yes.

12 Q Now, when you're reviewing peer-reviewed
13 research that's submitted to you, do you expect
14 the researchers to submit to you all the data that
15 they found, including the data that does not agree
16 with their hypothesis?

17 MR. SCOTT: Object as to form.

18 THE WITNESS: Again, I think it
19 depends on -- it's case by case. It depends
20 on what they're reporting and what the study
21 is. If it's, you know, something that
22 requires that level of specificity, most
23 certainly, or there should be a way to access
24 supplemental files, which has been my
25 experience as a peer reviewer. So if there's

1 Daniel Fabricant, Ph.D.

2 Q And does the fact that a piece of
3 research that you're peer reviewing is funded by a
4 company, does that make it, in your view,
5 scientifically invalid or worthy of less respect
6 or worth?

7 A It could. Again, it's case by case. It
8 depends on what gets presented.

9 Q And is it, in your mind, inappropriate
10 for the organization that's funding research to
11 comment on the research as it's being performed?

12 MR. SCOTT: Object as to form.

13 THE WITNESS: Again, it's case by
14 case. In some instances that may be true.

15 In other instances it may not be. It depends
16 on a lot of factors.

17 BY MR. WENIK:

18 Q When you were a peer reviewer, have you
19 seen where the sponsors of research have commented
20 on the manuscript, edited the manuscript?

21 A Yes.

22 Q Does that in and of itself detract from
23 the validity of the research in your mind?

24 A It has in some instances. In other
25 instances it hasn't. It depends again on -- it's

1 Daniel Fabricant, Ph.D.

2 supplemental information that generally is
3 available, that usually satisfies most of the
4 questions. However, you know, it's case by
5 case.

6 BY MR. WENIK:

7 Q Would you consider it a breach of the
8 scientific method for a researcher to exclude from
9 his or her manuscript only that data that
10 disagreed with his hypothesis?

11 MR. SCOTT: Object as to form.

12 THE WITNESS: Again, I think it's
13 case by case. Depends on the study. I can
14 envision scenarios where you wouldn't
15 necessarily include everything, and I can
16 envision scenarios where you want to include
17 everything.

18 BY MR. WENIK:

19 Q When you published peer-reviewed
20 articles, did you submit all the data of your
21 findings to the peer reviews?

22 A Sometimes yes, sometimes no. Sometimes
23 it wasn't, at least in our opinion, essential and
24 necessary for the publication.

25 Q Did you ever engage in a process where

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1 Daniel Fabricant, Ph.D.
 2 you selectively excluded only information that
 3 disagreed with your hypothesis?
 4 A I'm not sure I understand the question.
 5 Q You said that sometimes you would say
 6 some information would not be essential; is that
 7 right?
 8 A Yes.
 9 Q All right. Would you deem information
 10 not being essential only that which disagreed with
 11 whatever hypothesis you had for your research?
 12 A Again, it's case by case. It depends on
 13 what the hypothesis is. If the hypothesis is so
 14 broad, you may not need every piece of information
 15 there. So again, it's case by case. It depends
 16 on the scenario.
 17 Q Would you consider it an act of
 18 scientific dishonesty to falsify the results you
 19 published in a -- that one published in a
 20 peer-reviewed paper?
 21 A Yes.
 22 Q Would you consider it an act of
 23 scientific dishonesty to present a PowerPoint
 24 presentation at a conference that contained
 25 falsified information?

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1 Daniel Fabricant, Ph.D.
 2 Q Did she in particular send you emails
 3 about what her opinions were regarding DMAA?
 4 A I believe she did.
 5 Q What is the relationship, if any,
 6 between the FDA and the U.S. Anti-Doping Agency?
 7 A Other than we both get our funding from
 8 Congress, none.
 9 Q Did officials of the U.S. Anti-Doping
 10 Agency attend any policy meetings at the FDA?
 11 MR. SCOTT: Object as to form.
 12 THE WITNESS: Would you elaborate
 13 on what you mean by "policy meetings"?
 14 BY MR. WENIK:
 15 Q Well, let me make it broad. Did they
 16 attend any meetings at the FDA, to your knowledge,
 17 U.S. Anti-Doping officials?
 18 MR. SCOTT: You're talking about
 19 when he was there?
 20 BY MR. WENIK:
 21 Q Yes.
 22 A I believe there was a public hearing on
 23 some Food Safety Modernization Act rules that they
 24 may have attended.
 25 Q Did they attend internal FDA meetings

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1 Daniel Fabricant, Ph.D.
 2 A Yes.
 3 Q Do you know an individual named Amy
 4 Eichner?
 5 A I know of Amy, yes.
 6 Q Who is Amy Eichner?
 7 A She works for the U.S. Anti-Doping
 8 Agency.
 9 Q And what is your understanding of what
 10 her position is with that organization?
 11 A She's a research chemist.
 12 Q And during your tenure at the FDA,
 13 during that February of 2011 to April of 2014
 14 period, did you have interactions with
 15 Ms. Eichner?
 16 A We saw her at national meetings, and she
 17 liked to send us emails.
 18 Q And what would be generally the subject
 19 matters of her emails to FDA?
 20 A As many people do, they, you know,
 21 people -- FDA I like to describe as a big slow
 22 moving target that bleeds when you hit it, so
 23 people tended to want to give FDA their opinions
 24 of what they thought FDA's priorities should be,
 25 and Ms. Eichner engaged in that sometimes.

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1 Daniel Fabricant, Ph.D.
 2 during your tenure?
 3 MR. SCOTT: Object as to form.
 4 THE WITNESS: No.
 5 BY MR. WENIK:
 6 Q Did you have teleconferences with
 7 Ms. Eichner during your tenure at the FDA?
 8 A I spoke with her on the phone a number
 9 of times.
 10 Q Did you speak with her about DMAA?
 11 A Can you clarify a little bit?
 12 Q Did she speak to you about her concerns
 13 about DMAA?
 14 A Sure.
 15 Q And was one of her concerns that DMAA
 16 posed a health risk?
 17 A Mm-hmm, yes.
 18 Q And were you aware of public speeches
 19 that Ms. Eichner was making in 2011 and 2012
 20 regarding the purported dangers of DMAA?
 21 A Yes.
 22 Q So I'd like to turn your attention to --
 23 I'm going to get the title right -- the National
 24 Center for Natural Products Research at the
 25 University of Mississippi.

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1 Daniel Fabricant, Ph.D.
 2 Is this an entity that you're familiar
 3 with?
 4 A Yes.
 5 Q How are you familiar with this entity?
 6 A There was money earmarked,
 7 technically -- you can't call it earmarked
 8 anymore -- by Senator Thad Cochran that
 9 established that as a center of excellence for
 10 FDA, and there was pass-through money given every
 11 year that FDA administered to the National Center
 12 for Natural Products Research that I was in charge
 13 of. I was the program officer.
 14 Q Let me show you an email.
 15 (Exhibit 3 was marked for
 16 identification.)
 17 BY MR. WENIK:
 18 Q Okay. Dr. Fabricant, I've put before
 19 you an email chain that I marked as Fabricant
 20 Exhibit 3, but before I even get to the email
 21 chain, I should lay a couple of foundational
 22 questions for it. So we've been talking about --
 23 MR. SCOTT: Let me raise an issue
 24 here. I don't think this is my document.
 25 This confidentiality designation, the

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1 Daniel Fabricant, Ph.D.
 2 in violation of the protective order.
 3 MR. WENIK: Well, it's a violation
 4 if it goes to the public.
 5 MR. SCOTT: Well, it's a violation
 6 to use it. Dr. Fabricant is not under the
 7 protective order.
 8 MR. WENIK: Well, if he's part of
 9 FDA.
 10 MR. SCOTT: He is not part of FDA
 11 at this point in time. He's a former
 12 employee.
 13 MR. WENIK: Well, you have your
 14 objection.
 15 MR. SCOTT: I have my objection,
 16 and I'll have to let Mississippi know that
 17 this has been used in here, and they can take
 18 whatever action they want, but this is not my
 19 document. That's my point. Not my
 20 designation. I can double-check that, but
 21 I'm pretty sure that's -- I'm almost positive
 22 that's the case.
 23 MR. WENIK: All right. Fair
 24 enough.
 25 THE WITNESS: Should I answer the

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1 Daniel Fabricant, Ph.D.
 2 numbers I can go double-check, but I believe
 3 this is designated by the University of
 4 Mississippi.
 5 MR. WENIK: My understanding is
 6 that James Harlow and (person) at the
 7 University of Mississippi jointly designated
 8 certain things as confidential.
 9 MR. SCOTT: My understanding was
 10 that, no, we went through and looked at
 11 things that were privileged, but the
 12 designations were from the University of
 13 Mississippi. We did not designate it
 14 confidential. So this is Mississippi's
 15 document. They designated it confidential,
 16 so I have no right to agree that you can use
 17 it on the record, because there's
 18 confidentiality on it. This is not something
 19 that I can deal with at the end, because it's
 20 not my document.
 21 MR. WENIK: You want to pose an
 22 objection to its use?
 23 MR. SCOTT: I guess I have to,
 24 because the protective order is in place, and
 25 unless you cleared it with them, I think it's

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1 Daniel Fabricant, Ph.D.
 2 question?
 3 BY MR. WENIK:
 4 Q I didn't ask you anything yet.
 5 A I'm not on the protective order. I
 6 don't want to get myself in any trouble.
 7 MR. SCOTT: I don't want to get
 8 myself in trouble either by allowing the
 9 witness to answer something that's -- let's
 10 take a break and let me check with James on
 11 the status of these things.
 12 MR. WENIK: I think the protective
 13 order permits us to use these things at
 14 deposition but just not be filed in public.
 15 MR. SCOTT: I think the order
 16 allows us to use things in deposition to the
 17 extent that they are presented to people who
 18 are covered by the protective order. For
 19 example, experts have to sign a designation
 20 saying they will comply with it.
 21 MR. WENIK: Well, we can have
 22 Dr. Fabricant sign one.
 23 MR. SCOTT: I don't think he
 24 qualifies under the protective order, because
 25 he's not a current employee and he's not an

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1 Daniel Fabricant, Ph.D.
 2 expert, and there are certain categories of
 3 people who can and cannot access. That's why
 4 I want to get the protective order, check on
 5 the status of it, and then we'll go from
 6 there. Sorry to raise the issue, but I'm
 7 just not entirely comfortable with where we
 8 are at the moment.
 9 (Whereupon, a short recess was
 10 taken.)
 11 MR. SCOTT: We took a break so I
 12 could check the status of our document that's
 13 been marked as Exhibit 3. This is not a
 14 government-produced document. This was
 15 produced by the University of Mississippi.
 16 Now, the University of Mississippi
 17 made the designations of confidential. We
 18 did not, and we did not have any input in
 19 that. That was solely theirs.
 20 What we have done in coordination
 21 with them is review materials that they were
 22 producing to ensure they didn't turn over
 23 anything that was privileged based on the
 24 retention of Dr. Khan as an expert with us.
 25 Now, under the protective order, as

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1 Daniel Fabricant, Ph.D.
 2 then you're good.
 3 BY MR. WENIK:
 4 Q Okay. I'm glad we resolved that. So
 5 let me ask you a couple of foundational questions
 6 before I ask you to hook at that, Doctor.
 7 So first of all, a gentleman by the name
 8 of Mahmoud ElSohly, is that somebody that you're
 9 acquainted with?
 10 A Yes.
 11 Q Is it your understanding that
 12 Dr. ElSohly is affiliated in one way, shape or
 13 form with the National Center for Natural Products
 14 Research?
 15 A I was aware he was at the University of
 16 Mississippi.
 17 Q And Ikhlas Khan, is Dr. Khan someone
 18 that you're acquainted with?
 19 A Yes.
 20 Q And is it your understanding that
 21 Dr. Khan is affiliated with the National Center
 22 for Natural Products Research at the University of
 23 Mississippi?
 24 A Yes.
 25 Q Okay. Now that I've asked those

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1 Daniel Fabricant, Ph.D.
 2 a former employee, it's my reading that
 3 Dr. Fabricant would not be allowed to sign
 4 the protective order and be covered.
 5 Now, having said that, for this
 6 document it's not an issue as I read it,
 7 because in section 3E, anyone who had access
 8 to the document prior to the litigation does
 9 not have to be signed up under the protective
 10 order. So for this document you can question
 11 the witness.
 12 MR. WENIK: And similarly, I take
 13 it --
 14 MR. SCOTT: If he's on them, yes.
 15 If he's not on them, I suggest your office
 16 call the University of Mississippi and work
 17 something out, because I'm hesitant to have
 18 him talk about documents that he should not
 19 have official access to under the protective
 20 order.
 21 MR. WENIK: I hear you. I think
 22 everything I have is something you've
 23 already -- that your name is on it in some
 24 fashion.
 25 MR. SCOTT: If that's the case,

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1 Daniel Fabricant, Ph.D.
 2 questions, now I can turn my attention to
 3 Fabricant Exhibit 3, which is an email chain
 4 between Dr. Khan and yourself.
 5 First of all, have you looked at this?
 6 Does this refresh your recollection of having had
 7 some email communications with Dr. Khan?
 8 MR. SCOTT: Be sure you read the
 9 whole thing to understand the context.
 10 THE WITNESS: Yes.
 11 BY MR. WENIK:
 12 Q And you mentioned before that there were
 13 some federal government monies that would be
 14 administered, for lack of a better word, by the
 15 FDA for the National Center for Natural Products
 16 Research.
 17 Is that some of what's being referred to
 18 in the email chain here in Fabricant Exhibit 3?
 19 A Yes. We were on a continuing resolution
 20 in 2012. The University of Mississippi was not on
 21 a continuing resolution and needed our budget
 22 numbers, as the two fiscal cycles didn't always
 23 coincide. So that's what this email refers to.
 24 Q And they had to fill out some sort of --
 25 I don't know -- grant proposal or other paperwork

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<p>1 Daniel Fabricant, Ph.D. 2 to get their funding through you; is that right? 3 A There was a renewal process for the 4 center. 5 Q Okay. So let me ask you just to 6 interpret some of these things for me. I'm 7 looking in the middle of it. You wrote to 8 Dr. Khan, "yes, 300 from Diego plus 400 from us 9 plus 1.6 as the base." 10 So this 1.6, would that be \$1.6 million? 11 A Yes. 12 Q So the \$1.6 million as the base, is that 13 part of this FDA federal funding? 14 A Yes. 15 Q And 400, would that refer to \$400,000? 16 A Yes, in supplemental money. 17 Q From the government, okay, and what is 18 the 300 from Diego? What would that be referring 19 to? 20 A Diego was the program officer at the 21 Office of Cosmetics and Colors for University of 22 Mississippi, so I was the program officer for the 23 whole center, so they had some additional work 24 that they had money set aside for at the 25 University of Mississippi for research work.</p>	<p>1 Daniel Fabricant, Ph.D. 2 Q I see. Okay. 3 Have you heard of an entity known as 4 ElSohly Laboratories, Inc.? 5 A Yes. 6 Q What is your understanding of what that 7 entity is? 8 A That it's a -- I guess there's a 9 partnership with the university and Dr. ElSohly to 10 conduct some, I guess, you know, to be 11 semi-entrepreneurial, research-wise. 12 Q Did the FDA have any contractual 13 relationships with ElSohly Laboratories, Inc.? 14 A No. 15 Q Do you know whether Dr. Khan had an 16 ownership stake in ElSohly Laboratories? 17 A I don't know his -- I don't know the 18 financial arrangements. 19 Q Are you familiar with another entity 20 known as Phytochemical Services, Inc., or PSI? 21 A No. 22 Q And how about an entity known as 23 ChromaDex; is that an entity that you're familiar 24 with? 25 A Yes.</p>
Page 64	Page 65
<p>1 Daniel Fabricant, Ph.D. 2 Q How are you familiar with ChromaDex? 3 A I've known Frank Jaksch, the founder of 4 ChromaDex, since I was in graduate school, so for 5 about 20 years. ChromaDex is a company on my 6 current board. 7 Q And what is your understanding of what 8 ChromaDex does? 9 A A lot of different things. Produce fine 10 chemicals for food supplements, analytical testing 11 services, standard development, to name a few 12 things. 13 Q Does ChromaDex also manufacture dietary 14 supplements? 15 A Ingredients. 16 Q Do they manufacture ingredients that are 17 used in dietary supplements? 18 A Yes. 19 Q And was that true during your tenure at 20 the FDA, that they manufactured ingredients for 21 dietary supplements? 22 A I believe so. 23 Q Do you know whether Dr. Khan, Ikhlas 24 Khan, has any role or position with ChromaDex? 25 A He worked on pterostilbene, and I</p>	<p>1 Daniel Fabricant, Ph.D. 2 believe there was some technology-sharing between 3 the University of Mississippi and ChromaDex. 4 Q Do you know whether Dr. Khan has an 5 ownership stake in ChromaDex? 6 A I don't know what his financial 7 arrangements are. 8 Q What is your understanding of what 9 Dr. Khan's area of expertise is? 10 A Natural products research. He's world 11 renowned, once of the best natural products 12 scientists globally, phytochemistry to really 13 spanning -- it's a multidisciplinary field, so 14 spanning all those areas, and he's helped to 15 establish University of Mississippi as really a 16 leader in all those relevant areas. 17 Q Is his training as a chemist? 18 A Yes. 19 Q To your understanding, is he a clinician 20 at all? 21 A No, but he's been involved in clinical 22 studies. 23 Q And is he someone whose judgment you 24 trust? 25 A Yes.</p>

1 Daniel Fabricant, Ph.D.
 2 Q When you were at the FDA, is he somebody
 3 whose advice you sought out?
 4 MR. SCOTT: Object as to form.
 5 THE WITNESS: Amongst others, yes,
 6 scientifically.
 7 BY MR. WENIK:
 8 Q Would you feel he's a person of some
 9 integrity?
 10 A Yes.
 11 Q Let me ask you about Dr. ElSohly. What
 12 is your understanding of his area of expertise?
 13 A Dr. ElSohly is a very well-respected
 14 chemist, is one of the world leaders in banned
 15 substance testing of marijuana, cannabinoid
 16 ingredients, amongst other natural products, and
 17 is very adept at natural products research and has
 18 been for some time. Still holds a faculty
 19 position at the University of Mississippi and is
 20 very well-respected.
 21 Q Is he a clinician?
 22 A No.
 23 Q Is his training as a chemist?
 24 A Primarily, yes.
 25 Q And is he someone whose judgment you

1 Daniel Fabricant, Ph.D.
 2 MR. SCOTT: Same objection.
 3 THE WITNESS: I think putting drugs
 4 in the food supply is a danger.
 5 BY MR. WENIK:
 6 Q Okay. Is it your view that DMAA should
 7 be removed from the marketplace?
 8 MR. SCOTT: Same objection.
 9 THE WITNESS: DMAA, based on the
 10 letter of the law, based on the fact that it
 11 is a drug, shouldn't be available as a food.
 12 BY MR. WENIK:
 13 Q And was it your goal, when you were at
 14 the FDA, to have DMAA removed from the food
 15 supply?
 16 MR. SCOTT: Object as to form.
 17 THE WITNESS: My goal was to
 18 protect the public health, and any areas I
 19 saw as violative, to effectively enforce.
 20 BY MR. WENIK:
 21 Q And was one of the ways that you were
 22 seeking to protect the public health is to have
 23 DMAA removed from the food supply?
 24 A DMAA was violative of the Food, Drug &
 25 Cosmetic Act, so I would not be dispatching my

1 Daniel Fabricant, Ph.D.
 2 trust?
 3 A Yes.
 4 Q Did you seek his advice when you were at
 5 the FDA?
 6 MR. SCOTT: Object as to form.
 7 THE WITNESS: I spoke with a lot of
 8 scientists, yes.
 9 BY MR. WENIK:
 10 Q All right. So let me ask you just
 11 generally: Would it be fair to say that you
 12 believe that DMAA poses a serious health risk?
 13 MR. SCOTT: Object as to form.
 14 THE WITNESS: Again, I think the
 15 evidence shows that DMAA is in violation of
 16 federal law, and given that DMAA behaves like
 17 an amphetamine, as it was previously under --
 18 you know, as it was previously under an NDA
 19 to be sold as a drug, I'm unfamiliar with any
 20 drug that doesn't have side effects.
 21 BY MR. WENIK:
 22 Q But my question is: Putting aside the
 23 legality -- I understand your regulatory
 24 expertise. Do you feel as a scientist that this
 25 is something that poses a danger?

1 Daniel Fabricant, Ph.D.
 2 duties if there were things that were violative
 3 that the agency wasn't taking appropriate action
 4 on.
 5 Q So I take it your answer is yes, that
 6 this was something you wanted removed from the
 7 marketplace; you felt it violated the law, right?
 8 A What I said -- I didn't say it felt
 9 anything. I said it violated the law, and so we
 10 took appropriate action. There's a process for
 11 that. We followed the process.
 12 Q Is it your view that DMAA is not found
 13 in the geranium plant?
 14 MR. SCOTT: Same objection.
 15 THE WITNESS: Based on the evidence
 16 I've seen and the evidence we conducted and
 17 compiled at the agency, I think that again
 18 our understanding, based on that evidence, is
 19 that DMAA is not found in a plant.
 20 BY MR. WENIK:
 21 Q And when did you first come to that
 22 view, that analysis?
 23 A Well, I think we looked -- we had an
 24 initial memo leading out to the first warning
 25 letters, which established the regulatory

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1 Daniel Fabricant, Ph.D.
 2 questions regarding DMAA.
 3 (Exhibit 4 was marked for
 4 identification.)
 5 BY MR. WENIK:
 6 Q Let me show you this document. I've
 7 placed before you a document that I've marked for
 8 identification as Fabricant Exhibit 4, which is an
 9 email chain and an attached brief news story. If
 10 you could take a moment to look through that, I
 11 want to ask you a quick question.
 12 MR. SCOTT: Be sure to review it so
 13 you understand the context.
 14 (Witness peruses document.)
 15 THE WITNESS: Yes.
 16 BY MR. WENIK:
 17 Q All right. So from time to time when
 18 you were at the FDA, did you have contact with
 19 journalists?
 20 A Yes.
 21 Q And would one of those journalists be
 22 somebody who worked for a Tribune company?
 23 A Yes.
 24 Q So it appears that you wrote, back in
 25 July of 2012, "On DMAA, people were looking for

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q Doctor, I've placed before you two
 4 documents that I've marked for identification as
 5 Fabricant Exhibit 5 and Fabricant Exhibit 6.
 6 Fabricant Exhibit 5 is a copy of --
 7 MR. SCOTT: Jack, this one has got
 8 highlighting on it.
 9 MR. WENIK: That's all right.
 10 MR. SCOTT: Okay.
 11 BY MR. WENIK:
 12 Q Fabricant Exhibit 5 is a copy of an
 13 April 24, 2012 warning letter to USPlabs, and
 14 Fabricant Exhibit 6 is a copy of an April 18, 2013
 15 letter to USPlabs.
 16 So my first question to you is: Just
 17 looking at Fabricant Exhibit 5 for a moment, have
 18 you seen that document before, this warning
 19 letter?
 20 A Yes.
 21 Q All right, and were you involved in the
 22 preparation of this warning letter?
 23 A Yes.
 24 Q How were you involved in the preparation
 25 of this warning letter?

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1 Daniel Fabricant, Ph.D.
 2 the next big thing post-ephedra. Patrick Arnold
 3 of BALCO fame played a role."
 4 Do you see that?
 5 A Yes.
 6 Q What role, if any, do you think
 7 Mr. Arnold played in DMAA being out there for
 8 sale?
 9 A To our knowledge, when I was at the
 10 agency, there were some blogs where he discussed
 11 it, going back to 2007, 2006, that mentioned DMAA
 12 and how it was, you know, the latest and greatest
 13 thing.
 14 Q And what did you mean in this email by
 15 "the next big thing post-ephedra"?
 16 A That was I believe from -- one of my
 17 people looked at those blogs, and those were the
 18 words of Mr. Arnold.
 19 Q Okay. Was it your understanding at this
 20 time that DMAA was being -- well, withdraw it.
 21 (Exhibit 5 was marked for
 22 identification.)
 23 (Exhibit 6 was marked for
 24 identification.)
 25

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1 Daniel Fabricant, Ph.D.
 2 A We wrote the expert memo and obviously
 3 discussed with the Office of Compliance and the
 4 Office of Chief Counsel aspects of the letter and
 5 the memo.
 6 Q And was this something that you approved
 7 of its dissemination, this letter?
 8 A Yes.
 9 Q Okay, and then this letter here, the one
 10 I marked as Fabricant Exhibit 6, which is a letter
 11 dated April 18, 2013, my questions were -- well,
 12 first of all, have you seen this letter before?
 13 A Yes.
 14 Q And were you involved in the drafting of
 15 this letter in any way, shape or form?
 16 A Yes.
 17 Q And how were you involved in this
 18 letter?
 19 A Similar. We prepared the expert memo
 20 underneath it and worked with -- there's a process
 21 at FDA to work with the Office of Chief Counsel
 22 and Office of Compliance to ensure that things are
 23 accurate and consistent with FDA's authorities.
 24 Q All right, and I'm looking at Fabricant
 25 Exhibit 6, and the first sentence of this letter

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<p>1 Daniel Fabricant, Ph.D. 2 to USPlabs, it says that "We acknowledge receipt 3 of your letters dated May 15 and 17, 2012, 4 September 28, 2012, and January 14, 2013, which 5 respond to the April 24, 2012 FDA warning letter 6 issued to your firm." 7 Do you see that? 8 A Yes. 9 Q And my question to you is: So the 10 letters that USPlabs, that are referred to here 11 that responded to Fabricant Exhibit 5, at some 12 point when you were at the FDA, did you see those 13 letters, the USPlabs response? 14 A I saw their responses, yes. 15 Q Okay. 16 (Exhibit 7 was marked for 17 identification.) 18 BY MR. WENIK: 19 Q Doctor, I've placed before you a 20 document that I've marked for identification as 21 Fabricant Exhibit 7, which is five pages. I'll 22 describe it -- for lack of a better term, it looks 23 like talking points. If you could take a moment 24 to take a look at this. Then I'm going to ask you 25 a couple of questions.</p>	<p>1 Daniel Fabricant, Ph.D. 2 (Witness peruses document.) 3 THE WITNESS: Okay. 4 BY MR. WENIK: 5 Q All right. So I'm looking at page 4 of 6 this document, and there's a bold question. It 7 says, "Didn't you lobby for industry to weaken 8 these authorities in your previous position?" And 9 it says, "When I ran the Natural Products 10 Association, the big part of my job was to push 11 our members for greater compliance with the laws, 12 because consumers deserve safe products." 13 So my question is: Having looked at 14 that excerpt and looked at this document, is this 15 something that you've seen before? 16 A I believe I have. It was developed I 17 believe by our press office at FDA. 18 Q Did you have a role in helping to create 19 this document? 20 A Yes, somewhat, but it was still by our 21 press folks to be responsive to incoming 22 inquiries. 23 Q And did you review the talking points 24 from the press office? 25 A I don't know if this is the final</p>
<p>Page 76</p> <p>1 Daniel Fabricant, Ph.D. 2 version or not. I mean I'm sure I reviewed it, 3 but again not knowing if this is the final or not, 4 obviously I wouldn't -- you know, what's here 5 versus what may be in the final may be different 6 with my changes. 7 Q Okay. Fair enough. 8 So I'm looking at the first page of the 9 document, and it says, "One company [USPlabs] 10 submitted a response to our warning letter, 11 including studies purporting to show that DMAA is 12 a dietary ingredient. However, FDA's review found 13 this information insufficient. FDA is finalizing 14 a formal response to the company regarding the 15 additional information its lawyers submitted 16 following the FDA's warning letter." 17 Do you see that? 18 A Mm-hmm, yes. 19 Q So would it be fair to say that the 20 talking points are referring, when it says "FDA is 21 finalizing a formal response," that they're 22 referring to what ultimately became Fabricant 23 Exhibit 6, this April 18, 2013 letter, that that 24 was the formal response to USPlabs' letters? 25 A It may have been earlier in the process.</p>	<p>Page 77</p> <p>1 Daniel Fabricant, Ph.D. 2 Again, not knowing if this is the final or not, I 3 don't know that this bullet would have necessarily 4 stayed in a final version. It wasn't generally 5 our policy to discuss what was happening behind 6 the scenes, you know, for a variety of reasons. 7 So if you want me to speculate and say it's 8 referring to this one, sure, but we got -- 9 Q I guess my real point is -- would it be 10 fair to say that this document, the bullet points, 11 were prepared at some point in time prior to 12 April 18, 2013, prior to when the response went 13 out? 14 A Just because they were prepared, again I 15 don't know if this is -- I don't think this is the 16 final version, so just because somebody wrote 17 something down on a piece of paper doesn't mean 18 they were, you know, it was the -- again, this is, 19 this looks like a draft, if anything. 20 Q All right, but you would agree with me, 21 whether it's a draft or not, it was prepared 22 before this letter? 23 MR. SCOTT: Object as to form. 24 THE WITNESS: Again, not, not 25 having the dates. It could have been.</p>

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q Okay. Let me ask you to take a look at
 4 page 2 of the Fabricant Exhibit 7, and I'm looking
 5 at the third bullet point down from the top, and
 6 it says, "DMAA has known pharmacological effects
 7 on the human body -- it can narrow blood vessels
 8 and arteries."
 9 So let's take that first statement. Is
 10 that something that, based on the information that
 11 you've seen that you believe is true, that DMAA
 12 can narrow blood vessels and arteries?
 13 A That's the information based on
 14 Forthane's NDA when Forthane was used as a drug.
 15 Q So that would be the factual basis for
 16 that statement, the Forthane NDA?
 17 A Yeah, I mean that's a known
 18 pharmacological effect on the human body.
 19 Q Okay, and then it says "which can
 20 elevate blood pressure." Is that something, is
 21 that statement something that, based on what
 22 you've read, you believe is true?
 23 A If it narrows blood vessels and
 24 arteries, that elevates blood pressure.
 25 Q And then it says "can lead to

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1 Daniel Fabricant, Ph.D.
 2 that are out there on DMAA's safety for this
 3 particular . . .
 4 Q So the basis for saying that it could
 5 lead to heart attack would be the case reports and
 6 the NDA materials for Forthane?
 7 A Well, the NDA materials, that was by the
 8 people who made Forthane. That was one of their
 9 side effects, so yes.
 10 Q Let me direct you to the last three
 11 bullet points on page 2.
 12 So I'm looking at the third one from the
 13 bottom. It says, "The law does NOT give FDA
 14 pre-market approval to determine whether or not
 15 dietary supplements are safe or effective prior to
 16 marketing, unlike the laws for marketing drugs."
 17 Is that something you agree with?
 18 MR. SCOTT: Object as to form.
 19 Calls for a legal conclusion.
 20 MR. WENIK: He did say he was a
 21 regulatory expert.
 22 MR. SCOTT: I didn't direct him not
 23 to answer.
 24 BY MR. WENIK:
 25 Q Go ahead.

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1 Daniel Fabricant, Ph.D.
 2 cardiovascular problems ranging from shortening of
 3 breath and tightening in the chest to heart
 4 attack."
 5 That last phrase, is that something,
 6 based on what you've seen, that you believe is
 7 true?
 8 A Well, again, that's the pharmacology of
 9 what was submitted for Forthane. If you have an
 10 elevated blood pressure, that, of course, can lead
 11 to any of those. You know, that's what it says
 12 right here. If you elevate blood pressure, that
 13 can lead to cardiovascular problems, ranging from
 14 shortening of breath, tightening of the chest, to
 15 a heart attack. That's not a secret.
 16 Q Are you aware of any clinical studies
 17 showing DMAA causing heart attack?
 18 A We generally don't do clinical studies
 19 on people, since World War II, to show that
 20 something kills them. There are a lot of really
 21 good laws against that.
 22 Q Are you aware of any epidemiological
 23 studies showing that DMAA causes heart attack?
 24 A I think there's a variety of case
 25 reports, but I'm not speaking to the case reports

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1 Daniel Fabricant, Ph.D.
 2 A The law doesn't give FDA pre-market
 3 approval. It's a notification system.
 4 Q And then you wrote, "In most cases,
 5 companies do not even have to tell us about a
 6 product prior to selling it. The law only
 7 requires companies to notify FDA when they intend
 8 to market a dietary supplement containing a New
 9 Dietary Ingredient (NDI) in the United States, if
 10 the NDI has not been used in the food supply in
 11 the same chemical form."
 12 Do you agree with that statement?
 13 MR. SCOTT: Same objection.
 14 THE WITNESS: As it pertains to
 15 NDIs, yes.
 16 BY MR. WENIK:
 17 Q "An NDI is a dietary ingredient that was
 18 not marketed in a dietary supplement prior to
 19 October 15, 1994."
 20 Do you agree with that?
 21 A Yes.
 22 Q Then the second bullet from the bottom
 23 there, it say, "Under current law, manufacturers
 24 of dietary supplements are not required to prove
 25 the safety and efficacy of their products to FDA

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1 Daniel Fabricant, Ph.D.
 2 prior to marketing."
 3 Is that a statement you agree with?
 4 MR. SCOTT: Same objection.
 5 THE WITNESS: Yes.
 6 BY MR. WENIK:
 7 Q And the last bullet there says, "To ban
 8 a dietary supplement, FDA must clearly demonstrate
 9 that the product is adulterated (e.g., because it
 10 contains an unsafe food additive or presents a
 11 'significant or unreasonable risk' when used as
 12 directed the label)."
 13 Is that a statement you agree with?
 14 MR. SCOTT: Object as to form.
 15 THE WITNESS: Yeah, and these are
 16 talking points that were created by someone
 17 in the press office. I would have, I would
 18 have worded things slightly different. I
 19 think they kind of have the concept down.
 20 BY MR. WENIK:
 21 Q And it says, "This process can take
 22 years."
 23 Do you agree with that, that it could
 24 take years to formally ban an ingredient?
 25 A That's from the agency's experience.

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1 Daniel Fabricant, Ph.D.
 2 To the extent that you can answer
 3 the question based on public positions that
 4 have been taken by FDA, please do so, but if
 5 there are any -- if you have any information
 6 that's based on internal discussions that
 7 were not made public, then I direct you not
 8 to answer on that basis, based on the
 9 deliberative process privilege.
 10 THE WITNESS: Based on our
 11 findings -- we obviously researched that
 12 question. In terms of for a dietary
 13 supplement, geraniums did not appear to be on
 14 any of the grandfather lists in terms of
 15 being sold as a dietary supplement. Rose
 16 geranium oil we were familiar with as a food
 17 additive, which was pre-'94.
 18 BY MR. WENIK:
 19 Q All right. So just looking at this
 20 document as a reference point, for lack of a
 21 better word, Fabricant Exhibit 5, prior to
 22 April 24, 2012, prior to the issuance of that
 23 warning letter, were you made aware of the death
 24 of a military serviceman that was possibly linked
 25 to DMAA?

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1 Daniel Fabricant, Ph.D.
 2 However, that's specific to things that are
 3 dietary ingredients. They would have to be a
 4 dietary ingredient for the FDA to ban it. If it's
 5 not a dietary ingredient, well, then it doesn't
 6 belong in the food supply to begin with.
 7 Q Was it your belief, during your tenure
 8 at the FDA, that the FDA needed enhanced
 9 regulatory tools to conduct its mission regarding
 10 dietary supplements?
 11 A I didn't have an opinion. I was there
 12 to execute the authorities I did have.
 13 Q What is your opinion today as you sit
 14 here, part of the Natural Products Association?
 15 Do you think the FDA needs additional regulatory
 16 tools to deal with dietary supplements?
 17 A By and large, I think the laws are
 18 there, and they can certainly be used
 19 appropriately.
 20 Q Was it your position when you were in
 21 the FDA that geraniums were not in the food supply
 22 prior to October 15, 1994?
 23 A I have --
 24 MR. SCOTT: Let me object as to
 25 form.

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1 Daniel Fabricant, Ph.D.
 2 A Yes.
 3 Q And in the wake of that serviceman's
 4 death, were there news accounts about that
 5 incident?
 6 A Yes.
 7 Q And did you feel pressure from news
 8 media accounts to take some action regarding DMAA
 9 in the wake of those news reports regarding the
 10 death of this serviceman?
 11 A I think that's two questions.
 12 Q All right. Did you feel pressure from
 13 the media to take action against DMAA?
 14 MR. SCOTT: Object as to form.
 15 THE WITNESS: Yeah, that still
 16 seems like two questions.
 17 BY MR. WENIK:
 18 Q You were aware of the news reports
 19 regarding the serviceman's death; is that right?
 20 A Yes.
 21 Q Did those news reports in part encourage
 22 you to take action against DMAA?
 23 A No.
 24 Q Did individuals encourage you to take
 25 action against the DMAA from the public?

1 Daniel Fabricant, Ph.D.
 2 A Outside of FDA?
 3 Q Yes.
 4 A No.
 5 Q Were you receiving industry exhortations
 6 to take action against DMAA?
 7 MR. SCOTT: Object as to form.
 8 THE WITNESS: Sure. However, the
 9 fact remains. It was our burden to build a
 10 case, and we had a system, we worked the
 11 system, and this was -- you know, we had a
 12 variety of NDIs that we took action against.
 13 BY MR. WENIK:
 14 Q Are you familiar with a Harvard
 15 researcher named Pieter Cohen?
 16 A Yes.
 17 Q What is your familiarity with Dr. Cohen?
 18 A Dr. Cohen was a friend of the former
 19 deputy commissioner, Joshua Sharfstein, while I
 20 was at FDA, and I met Dr. Cohen through
 21 Dr. Sharfstein.
 22 Q Did you have conversations with
 23 Dr. Cohen about DMAA?
 24 A I did.
 25 Q Did he urge you to take action against

1 Daniel Fabricant, Ph.D.
 2 DMAA?
 3 A That was his opinion. A lot of people
 4 had opinions on DMAA.
 5 Q Is it your opinion that he's a reputable
 6 scientist?
 7 A Sometimes.
 8 Q I have to probe on that. At what times
 9 would you believe that Dr. Cohen is not a
 10 reputable scientist?
 11 A Look, he has an opinion. He feels he
 12 can be an advocate for public health by getting
 13 his opinion out. I don't always agree with that.
 14 However, he is, you know, reputable in terms of --
 15 the actual science he does is very reputable.
 16 Q Did his writings or opinions influence
 17 the actions you took regarding DMAA?
 18 A No. We have a process at the agency.
 19 We worked the process.
 20 Q Let me ask a couple more questions, and
 21 then we'll take a break.
 22 So take a look at Fabricant Exhibit 5
 23 for a moment, if you don't mind, and look at the
 24 second page, and I'm looking at the first
 25 paragraph from the top there. It says, "To the

1 Daniel Fabricant, Ph.D.
 2 best of FDA's knowledge, there is no information
 3 demonstrating that dimethylamylamine" -- which we
 4 call it "DMAA," correct --
 5 A Yes.
 6 Q -- "was lawfully marketed as a dietary
 7 ingredient in the United States before October 15,
 8 1994, nor is there information demonstrating that
 9 this ingredient has been present in the food
 10 supply as an article used for food in a form in
 11 which the food has not been chemically altered."
 12 Do you see that?
 13 A Yes.
 14 Q At the time this letter was written back
 15 in April 2012, what is your recollection of what
 16 the factual bases were that supported that
 17 statement in the letter?
 18 A We had a memo that looked for -- that
 19 established whether or not it was, based on the
 20 sources we had, whether or not it was in the diet.
 21 We couldn't search an unlimited universe, but we
 22 searched a pretty extensive universe, and that was
 23 what we established.
 24 Q When you say you were searching, were
 25 you searching for DMAA as that substance, were you

1 Daniel Fabricant, Ph.D.
 2 searching geraniums, or both?
 3 A We searched as DMAA, we searched as the
 4 other names of DMAA that were being used. And
 5 specific to the law, DMAA was the article in the
 6 diet, not geraniums, or at least that's what
 7 USPlabs was supposing.
 8 MR. WENIK: All right. Why don't
 9 we take a break, because we've been going now
 10 for a while. Stretch your legs, use the
 11 restroom.
 12 (Whereupon, a short recess was
 13 taken.)
 14 (Exhibit 8 was marked for
 15 identification.)
 16 BY MR. WENIK:
 17 Q Doctor, I placed before you a document
 18 that I've marked as Fabricant Exhibit 8, which is
 19 a document that was originally marked by the
 20 government at another deposition, and you'll see
 21 the first few pages are in a foreign language, and
 22 then there's a certified English translation of it
 23 that follows.
 24 And the document purports to be a
 25 memorandum from the DTU National Food Institute,

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<p>1 Daniel Fabricant, Ph.D. 2 which is a university in Denmark is my 3 understanding of what DTU is. 4 My simple question to you is: Is this 5 something that you've seen before? 6 A I believe I have. 7 Q And did you have this information at the 8 FDA at the time that Fabricant Exhibit 5 was 9 prepared, that kind of warning? Was this one of 10 the things that went into the basis for that 11 letter? 12 MR. SCOTT: Well, let me object and 13 ask for clarification. Are you talking about 14 the Li document? The translation is dated 15 August of 2016. 16 BY MR. WENIK: 17 Q Right. I assume you didn't have this 18 particular translation, but my question is: Did 19 you have some version of this, I guess is the 20 better question, when you put out this warning 21 letter? 22 A I would have to see our memo, but I 23 think -- again, I'd have to see the memo to 24 refresh for certain that we had -- again, I'd have 25 to see the memo for certain. It's all the</p>	<p>1 Daniel Fabricant, Ph.D. 2 references we had on the initial, for the initial 3 warning letter. This was one of them, so . . . 4 Q Okay. Was it the practice when you were 5 at the FDA that you would look at information from 6 abroad in making decisions? 7 A We'd look at -- again, we'd search a 8 variety of scientific information. You know, you 9 can never get the whole universe, but we tried to 10 get as much of it as we could. Yeah, if there 11 were papers, foreign papers, they certainly would 12 -- we'd look at them. 13 Q Okay, and how much weight would you give 14 to information from a foreign entity? 15 MR. SCOTT: Object as to form. 16 THE WITNESS: As with any 17 reference, it's case by case. It depends on 18 the quality of the work done. It depends on, 19 you know, the scientific rigor there. It 20 depends on a variety of things. Is it 21 peer-reviewed? Is it -- you know, what is 22 it? 23 (Exhibit 9 was marked for 24 identification.) 25</p>
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<p>1 Daniel Fabricant, Ph.D. 2 BY MR. WENIK: 3 Q Doctor, I've placed before you a 4 document that I marked for identification as 5 Fabricant Exhibit 9, and I'd ask you to take a 6 moment or two to take a look at it. It's an email 7 chain from May 11, 2011. 8 A Okay. 9 Q Have you seen this email chain before? 10 A Looks like I was copied on it. 11 Q All right. Do you know Philip Gregory? 12 A I've met Philip before, yes. 13 Q Who is Philip Gregory? 14 A He is the editor or creator of Natural 15 Medicines Database. 16 Q And what is your understanding of what 17 the Natural Medicines Database is? 18 A It's kind of an electronic newsletter. 19 It goes to health practitioners on dietary 20 supplements. 21 Q All right, and Patricia Deuster, are you 22 familiar with this individual? 23 A Yes. 24 Q Who is Patricia Deuster? 25 A She was a professor at UUHS, the</p>	<p>1 Daniel Fabricant, Ph.D. 2 University of Uniformed Health Services. 3 Q All right, and what is the relationship, 4 if any, between the FDA and this university? 5 A Formally? We had a -- as we have the, 6 uh, the Public Health Service, so there's a formal 7 MOU, memorandum of understanding that, where 8 appropriate, some information can be shared, but 9 it has to go through -- there was a program 10 officer for that at White Oak. 11 Q All right, and this particular email 12 talks about there being a report in the literature 13 of a "positive urine drug screen for amphetamine 14 and related substances in a patient taking this 15 ingredient. DMAA has structural similarities to 16 amphetamine," and then there's a citation to an 17 article called "Dimethylamylamine: A Drug Causing 18 Positive Immunoassay Results for Amphetamines." 19 Then there's a citation for a journal. 20 Do you see that? 21 A Yes. 22 Q That citation, that article, was that 23 something that you recall was looked at prior to 24 the issuance of this warning letter that we have 25 as Fabricant Exhibit 5?</p>

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<p>1 Daniel Fabricant, Ph.D.</p> <p>2 A It may have been. Again I'll have to</p> <p>3 see the memo and see everything that was cited</p> <p>4 there. We always list what we cite.</p> <p>5 Q And what's the significance in your mind</p> <p>6 of there being a positive screen for amphetamine</p> <p>7 perhaps caused by DMAA? What significance does</p> <p>8 that have for you?</p> <p>9 A Well, it would be, you know, for war</p> <p>10 fighters or for police officers or people like</p> <p>11 that, firefighters, you know, a false drug test</p> <p>12 that's, you know, that would be it, that if they</p> <p>13 got a drug test for this, for using amphetamines</p> <p>14 when they didn't use amphetamines, that would be</p> <p>15 the extent of it.</p> <p>16 Q Does that in and of itself raise any</p> <p>17 sort of safety concern to you, the fact that it</p> <p>18 may react to an immunoassay for amphetamines?</p> <p>19 A No. We already had the data from the</p> <p>20 Forthane submission at the agency before May 11,</p> <p>21 so it's, again, it's a data point, but it's not</p> <p>22 one that I think is -- you know, there were</p> <p>23 stronger data points.</p> <p>24 Q And would you agree with me that DMAA is</p> <p>25 something distinct and not the same as</p>	<p>1 Daniel Fabricant, Ph.D.</p> <p>2 amphetamine?</p> <p>3 MR. SCOTT: Object as to form.</p> <p>4 THE WITNESS: DMAA has some</p> <p>5 characteristics -- it's not methamphetamine,</p> <p>6 but it has some characteristics -- you know,</p> <p>7 it's a bronchodilator, a vasoconstrictor.</p> <p>8 Amphetamines do that as well, so it has some</p> <p>9 pharmacological functions like an</p> <p>10 amphetamine, but is it methamphetamine? No.</p> <p>11 BY MR. WENIK:</p> <p>12 Q Amphetamines and DMAA are two separate</p> <p>13 things, correct?</p> <p>14 MR. SCOTT: Object as to form.</p> <p>15 THE WITNESS: Again, we just talked</p> <p>16 through how some of them are related, how</p> <p>17 some of the pharmacological actions are</p> <p>18 related, vasoconstriction, bronchodilation.</p> <p>19 Those are related physiologically, so it</p> <p>20 displays some characteristics, and I think,</p> <p>21 you know, like I said, it's not</p> <p>22 methamphetamine, but it displays some</p> <p>23 characteristics of the class of compounds we</p> <p>24 know as amphetamines, and the structural --</p> <p>25 the structure is similar.</p>
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<p>1 Daniel Fabricant, Ph.D.</p> <p>2 BY MR. WENIK:</p> <p>3 Q Similar but not the same?</p> <p>4 MR. SCOTT: Same objection.</p> <p>5 THE WITNESS: It's not the same as</p> <p>6 methamphetamine.</p> <p>7 BY MR. WENIK:</p> <p>8 Q Different molecule? Different molecular</p> <p>9 structure, rather?</p> <p>10 A Than methamphetamine, yes.</p> <p>11 (Exhibit 10 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. WENIK:</p> <p>14 Q Doctor, I've placed before you a</p> <p>15 document that is marked for identification as</p> <p>16 Fabricant Exhibit 10, which appears to be an email</p> <p>17 chain between you and Corey Hilmas, amongst</p> <p>18 others, and if you could take a moment to look</p> <p>19 through it, I'll ask you a couple of questions.</p> <p>20 A I don't think it's an email chain. It's</p> <p>21 just me sending a document to Corey that somebody</p> <p>22 sent me.</p> <p>23 Q Correct.</p> <p>24 A So that's different. There's no --</p> <p>25 Q No, I didn't mean to suggest that you</p>	<p>1 Daniel Fabricant, Ph.D.</p> <p>2 drafted the email. It's something that you</p> <p>3 forwarded on. Let's just describe it that way.</p> <p>4 That's fair.</p> <p>5 So my question to you is: Looking at</p> <p>6 it, it says "from Daniel Fabricant" --</p> <p>7 MR. SCOTT: Are you finished</p> <p>8 reading it?</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. WENIK:</p> <p>11 Q To Corey Hilmas, so we've discussed</p> <p>12 already who Corey Hilmas is.</p> <p>13 Who is Ramadevi Gudi?</p> <p>14 A She was the acting lead for the New</p> <p>15 Dietary Ingredient review team at that time.</p> <p>16 Q Okay, and the subject line, I take it,</p> <p>17 is something that you drafted. "Forward: More</p> <p>18 data on Forthane/DMAA safety and DRUG data from</p> <p>19 the literature."</p> <p>20 Is that right?</p> <p>21 A No, I didn't draft that at all. It came</p> <p>22 from this email which I forwarded.</p> <p>23 Q So you just copied the --</p> <p>24 A I just forwarded it to my people.</p> <p>25 Q Okay. James Neal-Kababick; do you know</p>

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1 Daniel Fabricant, Ph.D.
 2 who that is?
 3 A Yes.
 4 Q Who is James Neal-Kababick?
 5 A He runs a lab called Flora Research.
 6 Q And what does Flora Research do?
 7 A They do a variety of testing in the
 8 dietary supplement industry.
 9 Q And what is your understanding of
 10 Mr. Kababick's area of expertise?
 11 A Analytical laboratory expertise, looking
 12 at, you know, looking at a variety of compounds
 13 that are out there.
 14 Q All right. Is this somebody that you
 15 knew from your days at the NPA prior to going to
 16 the FDA?
 17 A I think I first met Jim when I was in
 18 graduate school at University of Illinois.
 19 Q Was he studying at the same institutions
 20 you were?
 21 A No, but some of the meetings, there were
 22 overlaps. The American Society of Pharmacognosy,
 23 the American Chemical Society, things like that.
 24 There was some overlap.
 25 Q Okay. What's your understanding of

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1 Daniel Fabricant, Ph.D.
 2 document, he talks about "I can only hope that FDA
 3 is drawing back the bowstring on this and not
 4 ignoring what I think is a blatant attempt to sell
 5 yet another pharmaceutical drug dressed up as a
 6 dietary supplement."
 7 What was your understanding of what were
 8 the other pharmaceutical drug he was referring to
 9 there, your understanding, if you recall?
 10 A No idea.
 11 MR. SCOTT: Object as to form.
 12 THE WITNESS: Yeah, you should ask
 13 Jim.
 14 BY MR. WENIK:
 15 Q Oh, I will. We will.
 16 His deposition already took place?
 17 MR. SCOTT: Yes, last Friday.
 18 MR. WENIK: We probably did
 19 already.
 20 BY MR. WENIK:
 21 Q He wrote further on here, "I completely
 22 support Health Canada's position on this and their
 23 evaluation of the Ping paper."
 24 Do you see that?
 25 A Yes.

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1 Daniel Fabricant, Ph.D.
 2 Mr. Kababick's training, if any?
 3 A He, you know, is a chemist is my
 4 understanding of his training.
 5 Q Is he someone whose views you respect?
 6 A I mean his lab has been around a while,
 7 so I think, you know, he certainly has, seems to,
 8 you know, seems like -- I mean I don't think any
 9 one analytical lab does everything perfect, but he
 10 seems to do a good job.
 11 Q Does the information that you forwarded
 12 on here, is this information you considered in
 13 thinking about DMAA when you were at the FDA?
 14 MR. SCOTT: Object as to form.
 15 THE WITNESS: Yeah, I'm not sure
 16 what you're asking, because some of this
 17 information we already had. It was just a --
 18 again, I would get a lot of these things, and
 19 I wanted to make sure we kept a file on them.
 20 BY MR. WENIK:
 21 Q So I take it you reviewed what he said?
 22 A I read it, yeah, but again it's nothing
 23 we didn't already know from what was in -- you
 24 know, what FDA already had available to it.
 25 Q Okay. On the second page of this

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1 Daniel Fabricant, Ph.D.
 2 Q What is your understanding of what the
 3 Ping paper was?
 4 A Well, we evaluated the Ping paper in our
 5 first memo. It was a paper from '96 in a journal
 6 that I think is defunct, and from a researcher
 7 that no one has ever met, describing the presence
 8 of DMAA in geranium.
 9 Q All right, and would it be fair to say
 10 that at the time that the April 24, 2012 warning
 11 letter went out, that you did not believe that
 12 there was evidence of DMAA being present in
 13 geraniums?
 14 A Based on what we had seen and working
 15 through the process the way we had -- and again I
 16 believe you have that memo predating that. That's
 17 all laid out there. We followed the process and
 18 we moved ahead.
 19 Q But following the process, you didn't
 20 think that there was DMAA in geraniums at that
 21 time; is that right?
 22 A Well, the evidence suggested that DMAA
 23 was likely not from geraniums. Again, that's why
 24 we send the warning letter. This is a final
 25 agency action. It says if there is information

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<p>1 Daniel Fabricant, Ph.D. 2 available, they can provide it. USPlabs did on a 3 number of occasions, and it didn't rise up to the 4 level. 5 Q These old textbooks that Mr. Kababick 6 cites here, you believe that you had the benefit 7 of that information, the original source material? 8 MR. SCOTT: Object as to form. 9 THE WITNESS: I don't think it 10 would have gotten to or through the agency 11 without that material, yes. 12 BY MR. WENIK: 13 Q Did you have conversations with 14 Mr. Kababick about DMAA? 15 A A lot of people wanted to talk about 16 DMAA, okay? Just because people have an opinion 17 doesn't, you know, doesn't shape the agency's 18 actions. 19 Q Right, but my question is: Did you have 20 conversations with him about DMAA? 21 A I had conversations with people about a 22 lot of subjects. 23 Q Including Mr. Kababick? 24 A Yes. 25</p>	<p>1 Daniel Fabricant, Ph.D. 2 (Exhibit 11 was marked for 3 identification.) 4 (Exhibit 12 was marked for 5 identification.) 6 BY MR. WENIK: 7 Q All right, Dr. Fabricant, I've placed 8 before you two documents that I marked for 9 identification as Fabricant Exhibit 11 and 10 Fabricant Exhibit 12. 11 For the record, Fabricant Exhibit 11 is 12 an email between Patricia Deuster and a number of 13 recipients, including you, and Fabricant Exhibit 14 12 is a document from Health Canada regarding 15 DMAA. 16 So my first question to you is: Looking 17 at Fabricant Exhibit 11, that document, have you 18 seen this before, this email before? 19 A I was copied on the thread. 20 Q All right, and Patricia Deuster is 21 telling you that Health Canada has decided to 22 classify DMAA as a drug. 23 Do you see that? 24 A Yes. 25 Q Is it your understanding that what she</p>
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<p>1 Daniel Fabricant, Ph.D. 2 was referring to in this August 2, 2011 email was 3 what I put before you as Fabricant Exhibit 12, 4 that that was the decision of Health Canada? 5 A That's what she sent around. 6 Q All right, and this document, the 7 decision of Health Canada, is this something that 8 was considered by your division within the FDA at 9 the time that Fabricant Exhibit 5, this warning 10 letter, was being prepared? 11 A We had a preliminary -- we had a few 12 preliminary calls. We had an information-sharing 13 arrangement with Canada, the FDA does, and so we 14 had discussed it a number of times, and I think we 15 had a draft memo long before this, and some of 16 their references as well. 17 Q "Long before this" meaning Fabricant 18 Exhibit 12? You had a draft memo from Canada 19 before this? 20 MR. SCOTT: Exhibit 12 is the 21 document from Canada. A draft of that? 22 MR. WENIK: I think that's what he 23 said. That's why I'm trying to clarify. 24 MR. SCOTT: Oh, okay. 25 THE WITNESS: We had conversations</p>	<p>1 Daniel Fabricant, Ph.D. 2 regarding it leading up to this, you know, 3 bound by that arrangement with Health Canada. 4 We were familiar with this prior to this. 5 BY MR. WENIK: 6 Q Prior to Fabricant Exhibit 5? 7 A Yes. 8 Q All right. So let's look at the Health 9 Canada document for a moment if you don't mind. 10 So the second page under the discussion section, 11 it says, "DMAA is used in party pills," and my 12 question is: 13 At the time that your agency was 14 considering writing this April 24, 2012 warning 15 letter, Fabricant Exhibit 5, did you have any 16 information about DMAA being marketed as "party 17 pills" in the United States? 18 A We had seen some reports that it was 19 used as such. 20 Q In the United States, reports of it 21 being used as such in the United States as opposed 22 to other countries? 23 A We saw it from other countries, if 24 memory serves, but again I'd have to look at all 25 of our documents that went into the memo behind</p>

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<p>1 Daniel Fabricant, Ph.D.</p> <p>2 this, but we had, we had heard that that was one</p> <p>3 possible use of it.</p> <p>4 Q All right, and it says further on in the</p> <p>5 third line, it says, "DMAA is included on the</p> <p>6 World Anti-doping Agency's prohibited substance</p> <p>7 list as a stimulant."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q So my question to you is -- and you</p> <p>11 mentioned before your regulatory expertise --</p> <p>12 because a substance is banned by an anti-doping</p> <p>13 agency, does that fact in and of itself make it</p> <p>14 not a dietary ingredient?</p> <p>15 A No, that wasn't what made it not a</p> <p>16 dietary ingredient.</p> <p>17 Q And the fact that something is banned by</p> <p>18 an anti-doping agency, does that in and of itself</p> <p>19 mean that a substance is unsafe as opposed to</p> <p>20 conferring some competitive advantage?</p> <p>21 A No. Again, DMAA, our findings and based</p> <p>22 on this memo were it wasn't in the plan, based on</p> <p>23 what we found.</p> <p>24 Q Right, but let's step back for a minute</p> <p>25 from DMAA.</p>	<p>1 Daniel Fabricant, Ph.D.</p> <p>2 The fact just generally that something</p> <p>3 is banned by an anti-doping agency, that in and of</p> <p>4 itself doesn't mean that the entity is unsafe,</p> <p>5 does it?</p> <p>6 A No.</p> <p>7 Q Would you agree with me that the</p> <p>8 Canadian government has a different regulatory</p> <p>9 scheme for drugs and foods than the United States</p> <p>10 does?</p> <p>11 A Yes.</p> <p>12 (Exhibit 13 was marked for</p> <p>13 identification.)</p> <p>14 (Exhibit 14 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. WENIK:</p> <p>17 Q So, Doctor, I've placed before you a</p> <p>18 document that I marked for identification as</p> <p>19 Fabricant Exhibit 13, which for the record is a --</p> <p>20 I downloaded it from the FDA's archive content on</p> <p>21 their website, an April 27, 2012 press release,</p> <p>22 and Exhibit 14 appears to be the same document</p> <p>23 that you emailed to yourself back in April 27,</p> <p>24 2012, or maybe it was on your system back on</p> <p>25 April 27, 2012.</p>
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<p>1 Daniel Fabricant, Ph.D.</p> <p>2 Do you see that?</p> <p>3 A Yes.</p> <p>4 Q All right. So my question to you is:</p> <p>5 First of all, have you seen these documents</p> <p>6 before?</p> <p>7 A Yes.</p> <p>8 Q All right, and what is your</p> <p>9 understanding of what they are?</p> <p>10 A They are a press announcement regarding</p> <p>11 the ten warning letters that went out on DMAA.</p> <p>12 Q Okay. Did you have a role in helping to</p> <p>13 draft the press announcement regarding the warning</p> <p>14 letters that went out on DMAA?</p> <p>15 A Yes.</p> <p>16 Q What was your role in doing that?</p> <p>17 A Obviously we provided the expert memo</p> <p>18 underneath that to the press office and worked</p> <p>19 with them on drafting it.</p> <p>20 Q Okay, and I'm looking at Fabricant</p> <p>21 Exhibit 14, just because it's not cut off. It</p> <p>22 says, "'Before marketing products containing</p> <p>23 DMAA'" -- I'm looking at the second paragraph from</p> <p>24 the bottom -- "'manufacturers and distributors</p> <p>25 have a responsibility under the law to provide</p>	<p>1 Daniel Fabricant, Ph.D.</p> <p>2 evidence of the safety of their products. They</p> <p>3 haven't done that, and that makes the products</p> <p>4 adulterated,' said Daniel Fabricant, Ph.D.,</p> <p>5 director of the FDA's Dietary Supplement Program."</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Did you approve of that statement going</p> <p>9 into the press release?</p> <p>10 A Yes.</p> <p>11 Q All right.</p> <p>12 If we look at the warning letters or</p> <p>13 rather the list in the press release of the</p> <p>14 warning letters, it does not include under the</p> <p>15 list of companies Hi-Tech Pharmaceuticals, does</p> <p>16 it?</p> <p>17 A No.</p> <p>18 Q Okay. So Hi-Tech is not here, and</p> <p>19 neither are any Hi-Tech products listed here, are</p> <p>20 there?</p> <p>21 A No.</p> <p>22 Q Let me rephrase that.</p> <p>23 Would you agree with me that Hi-Tech</p> <p>24 Pharmaceuticals is not on the list of companies in</p> <p>25 the press release?</p>

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1 Daniel Fabricant, Ph.D.
 2 A Yes.
 3 Q Would you agree with me that the press
 4 release doesn't list any Hi-Tech products?
 5 A Yes.
 6 Q Okay. Do you believe the press release
 7 is accurate?
 8 MR. SCOTT: Object as to form.
 9 THE WITNESS: Yes. It talks about
 10 the actions that were taken by the agency.
 11 (Exhibit 15 was marked for
 12 identification.)
 13 BY MR. WENIK:
 14 Q So, Dr. Fabricant, I've placed before
 15 you a document that I've marked for identification
 16 as Fabricant Exhibit 15, which looks like a news
 17 article that's been incorporated into an email
 18 chain back on April 27 of 2012.
 19 Do you see this?
 20 A Mm-hmm, yes.
 21 Q And are you in the email chain, your
 22 name?
 23 A Yes, I am.
 24 Q Are you familiar with an individual
 25 known as Steve Mister?

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1 Daniel Fabricant, Ph.D.
 2 And then further on there's a quote
 3 from him. "I don't see this as a black and white
 4 issue. There are many shades of gray."
 5 And in the email chain you said that,
 6 quote, "Can you believe Steve Mister? What a
 7 putz!"
 8 My question to you is: Putting aside
 9 the translation of the Yiddish word "putz," what
 10 were you referring to -- what was your -- what
 11 was your -- referring to is your incredulity
 12 regarding Mr. Mister's statement, what was he
 13 referring to?
 14 MR. SCOTT: Objection as to form.
 15 THE WITNESS: I had a conversation
 16 with Steve Mister earlier in 2012. He
 17 actually called the agency to inquire about
 18 if we were taking action on DMAA. So I found
 19 it a little interesting that, you know, he
 20 was trying to get information out of the
 21 agency, which he didn't, and now seemed to be
 22 politicizing the agency's action, so to
 23 speak, in his comments, his quotes.
 24 (Exhibit 16 was marked for
 25 identification.)

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1 Daniel Fabricant, Ph.D.
 2 A I am.
 3 Q How do you know Mr. Mister?
 4 A He is the CEO of the Council for
 5 Responsible Nutrition.
 6 Q And what is the Council for Responsible
 7 Nutrition?
 8 A It is a supplement trade association.
 9 Q And that's something distinct from
 10 separate from the Natural Products Association?
 11 A They are separate. I'd like to think
 12 that, yes, we are very distinct. They tend to
 13 represent more of, more of MLM type companies,
 14 multilevel marketing, not necessarily as involved
 15 in retail as my organization.
 16 Q All right, and look at the second page
 17 of the document, and at the bottom third of the
 18 page, there are some quotations from Mr. Mister,
 19 and he says, amongst other things, that "'The CRN
 20 has no vested interest in DMAA,' he said, but
 21 added: 'We've always said we don't want to rush
 22 to judgment on this. The science of this has to
 23 play out, and hopefully this is now an opportunity
 24 for the companies listed to give us some more
 25 clarity.'"

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q Dr. Fabricant, I've placed before you a
 4 document that I've marked for identification as
 5 Fabricant Exhibit 16, which is a memorandum from a
 6 Louis Carlacci and Ying Lin to you, dated May 17,
 7 2012, and it's a 12-page document, and I don't
 8 have a lot of detailed questions about it, but
 9 feel free to take a look at it.
 10 My first question is: Is this something
 11 that you recall seeing?
 12 A Yes.
 13 Q All right. Who is Louis Carlacci?
 14 A He was a reviewer on the NDI team, a
 15 chemist.
 16 Q And who is Ying Lin?
 17 A Ying Lin was originally an ORISE fellow,
 18 Oak Ridge Institute of Science, who was brought in
 19 as a chemist.
 20 Q And they were both -- these are both FDA
 21 employees, I take it?
 22 A Yes, in the division.
 23 Q All right, and their expertise was in
 24 chemistry for both of them?
 25 A Yes.

<p style="text-align: right;">Page 114</p> <p>1 Daniel Fabricant, Ph.D.</p> <p>2 Q And they directed this memorandum to you</p> <p>3 and Corey Hilmas. Did you direct them to prepare</p> <p>4 this memorandum?</p> <p>5 A Yes.</p> <p>6 Q And what was the purpose of creating</p> <p>7 this memorandum?</p> <p>8 A They did a further dive on some of the</p> <p>9 chromatography with regard to the Ping study. We</p> <p>10 had, again, had a meeting with Peter Hutt, who was</p> <p>11 USPlabs' counsel at the time, where he raised the</p> <p>12 Ping study a number of times.</p> <p>13 And so while our initial, you know, our</p> <p>14 initial -- and this memo was after the first</p> <p>15 warning letter. We had an original read on Ping,</p> <p>16 but we dove further as it was ongoing, and we got</p> <p>17 more information. Ying also, given that she is a</p> <p>18 native Chinese speaker, was very helpful in that</p> <p>19 regard in translating the original text.</p> <p>20 Q So if I understand your answer, do you</p> <p>21 believe that somebody had taken a look -- somebody</p> <p>22 within the FDA, rather, had taken a look at the</p> <p>23 Ping study before the April 24, 2012 warning</p> <p>24 letters went out, or did you look at the Ping</p> <p>25 study for the first time afterward as part of this</p>	<p style="text-align: right;">Page 115</p> <p>1 Daniel Fabricant, Ph.D.</p> <p>2 memorandum that we're looking at that's identified</p> <p>3 as Fabricant Exhibit 16?</p> <p>4 A We looked at the Ping study long before</p> <p>5 this letter. This is just a deeper dive, and Ying</p> <p>6 made some very good corrections in terms of -- or</p> <p>7 found a lot of errors in a deeper dive on the Ping</p> <p>8 study.</p> <p>9 Q Do you know how long it took them to</p> <p>10 prepare this analysis? Do you recall whether it</p> <p>11 was weeks or days or months?</p> <p>12 A Weeks, I believe, but again I'd have to</p> <p>13 see the thread there to be sure.</p> <p>14 (Exhibit 17 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. WENIK:</p> <p>17 Q So, Dr. Fabricant, I've placed before</p> <p>18 you a document I've marked for identification as</p> <p>19 Fabricant Exhibit 17, which is a copy of a paper</p> <p>20 that was published in the Journal of Analytical</p> <p>21 Toxicology by a number of authors, including</p> <p>22 Mahmoud ElSohly and Ikhlas Khan, who we spoke</p> <p>23 about earlier.</p> <p>24 My first question to you is: Have you</p> <p>25 seen this paper before?</p>
<p style="text-align: right;">Page 116</p> <p>1 Daniel Fabricant, Ph.D.</p> <p>2 A Yes.</p> <p>3 Q Now, if you look at the top of the</p> <p>4 document, it says that it was initially published</p> <p>5 on June 25, 2012, which would have been after the</p> <p>6 date of the warning letter Fabricant filed that</p> <p>7 was April 24, 2012. Do you see that?</p> <p>8 A Yes.</p> <p>9 Q My next question then would be: Did you</p> <p>10 have access to the data underlying this paper or</p> <p>11 manuscript or draft of it prior to the warning</p> <p>12 letter that was issued on April 24, 2012?</p> <p>13 MR. SCOTT: Object as to form.</p> <p>14 THE WITNESS: When you say "data,"</p> <p>15 do you mean were we knowledgeable that they</p> <p>16 were doing a study or final data?</p> <p>17 BY MR. WENIK:</p> <p>18 Q Let's take it in parts.</p> <p>19 First, were you knowledgeable that the</p> <p>20 National Center for Natural Products Research was</p> <p>21 conducting this study?</p> <p>22 A We were knowledgeable they were looking</p> <p>23 into DMAA, as well as were a number of people at</p> <p>24 the time.</p> <p>25 Q All right, and my second question then</p>	<p style="text-align: right;">Page 117</p> <p>1 Daniel Fabricant, Ph.D.</p> <p>2 would be: Did you have access to some of their</p> <p>3 preliminary findings or data prior to the issuance</p> <p>4 of this warning letter that we've marked as</p> <p>5 Fabricant Exhibit 5?</p> <p>6 A No, not that I recall.</p> <p>7 Q All right.</p> <p>8 Now, this article talks about</p> <p>9 Pelargonium oil and methyl hexaneamine or MHA.</p> <p>10 Would you agree with me that methyl hexaneamine or</p> <p>11 MHA is just a synonym for DMAA?</p> <p>12 A It is.</p> <p>13 Q And if we look at the very last page of</p> <p>14 the document, there's an acknowledgements section.</p> <p>15 It says that "this project was supported in part</p> <p>16 by the U.S. Anti-Doping Agency in Colorado</p> <p>17 Springs."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q Were you aware that the anti-doping</p> <p>21 agency was providing some funding for this work?</p> <p>22 MR. SCOTT: Objection. Time frame.</p> <p>23 THE WITNESS: Yeah.</p> <p>24 BY MR. WENIK:</p> <p>25 Q There's a fair objection.</p>

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1 Daniel Fabricant, Ph.D.
 2 Were you aware around, in the spring of
 3 2012, that the anti-doping agency was providing
 4 some funding for this research?
 5 A Honestly, I couldn't remember when
 6 exactly we knew that. You know, it didn't make a
 7 difference in terms of the warning letter. I
 8 mean --
 9 Q Would it be fair to say that the lion's
 10 share of the funding would have come through the
 11 FDA via support from the National Center for
 12 Natural Products Research?
 13 A I wouldn't say that's correct, no.
 14 Q Would the FDA have provided some of the
 15 funding for this project?
 16 A Again, I, I'm -- not having what was
 17 budgeted and those sorts of things, the
 18 line-by-line items, I'm not going to speculate to
 19 that. Obviously, the agency provided a lot of
 20 funding to the university over the years. To the
 21 extent that equipment was used, facilities were
 22 used that was supported by agency funding, okay,
 23 but no.
 24 Q I'm going to talk a little bit more
 25 about Dr. ElSohly. Do you know if he has any

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1 Daniel Fabricant, Ph.D.
 2 Q Refresh my recollection. Did you say
 3 you didn't know?
 4 A I didn't know.
 5 Q Okay, but would you agree with me that
 6 their primary expertise is chemistry?
 7 MR. SCOTT: Symptom.
 8 THE WITNESS: Again, natural
 9 products chemistry is largely what they're
 10 known for, but it's a multidisciplinary
 11 science.
 12 BY MR. WENIK:
 13 Q Do you know whether Dr. Khan has any
 14 legal training?
 15 MR. SCOTT: Object as to form.
 16 THE WITNESS: I don't know.
 17 BY MR. WENIK:
 18 Q How about Dr. ElSohly?
 19 A I don't know.
 20 MR. SCOTT: Same objection.
 21 BY MR. WENIK:
 22 Q All right. Take a look at page 12 of
 23 the article, and let me ask this foundational
 24 question before I ask you the question about page
 25 12.

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1 Daniel Fabricant, Ph.D.
 2 training in toxicology?
 3 A I think you may want to -- well --
 4 MR. SCOTT: Object as to form. If
 5 you know, you know, but don't speculate.
 6 BY MR. WENIK:
 7 Q No, I don't want you to speculate. If
 8 you don't know --
 9 A I don't want to speculate.
 10 Q Do you know whether he had any training
 11 in epidemiology?
 12 A I'm not going to speculate.
 13 Q How about pharmacology?
 14 A He was a professor of pharmacology.
 15 Q All right. Let's take Dr. Khan. Do you
 16 know whether he has any training in epidemiology?
 17 A I don't.
 18 Q Toxicology?
 19 A He's published quite a bit of
 20 toxicological research.
 21 Q Epidemiology?
 22 A You asked that already.
 23 Q For Khan? I don't think I asked that
 24 for Khan.
 25 A Yeah.

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1 Daniel Fabricant, Ph.D.
 2 Did you provide any feedback or review
 3 of drafts of this article before it became
 4 published, "you" meaning you personally, not the
 5 FDA?
 6 A I don't believe so.
 7 Q Do you know whether anyone else in the
 8 FDA provided any editing or comments to drafts of
 9 this article before it was published?
 10 A Not that I know of.
 11 Q All right.
 12 Looking at page 12, and on the column to
 13 the right, there's a paragraph that begins "a
 14 dietary supplement, according to DSHEA, is a
 15 product that is labeled as a dietary supplement
 16 and is not represented for use as a food or as a
 17 cure for any disease," and then there's a
 18 discussion about DSHEA and NDI that goes to the
 19 bottom of that page and a little bit over to the
 20 next page.
 21 Do you see that?
 22 A Yes.
 23 Q All right. When you read this document,
 24 when you saw this study, did you find it somewhat
 25 odd that chemists were commenting on DSHEA and its

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<p>1 Daniel Fabricant, Ph.D. 2 interpretation? 3 A It happens frequently in the dietary 4 supplement arena. People mention regulatory 5 status frequently, whether or not it's correct, 6 but it is mentioned frequently. 7 Q Do you consider either of these 8 gentleman, Khan or ElSohly, regulatory experts? 9 MR. SCOTT: Object as to form. 10 THE WITNESS: I mean they're very 11 good chemists. Regulatory experts? Again, 12 they've never worked at the agency, so I 13 wouldn't -- I think they have some general 14 knowledge. They help training inspectors, 15 they do things that are available, so in some 16 vein, yeah, they are regulatory experts. 17 University of Mississippi still helps to 18 train FDA inspectors. 19 So they are very familiar with the 20 agency. We certainly provided training to 21 them over the years when I was at the agency, 22 so I think they're knowledgeable. 23 BY MR. WENIK: 24 Q Take a look at the next page, page 13. 25 I'm looking at the right-hand column, and it says,</p>	<p>1 Daniel Fabricant, Ph.D. 2 "There is reasonable cause for concern regarding 3 the safety of MHA, given two published case 4 reports in which ingestion of MHA resulted in 5 severe adverse events, including cerebral 6 hemorrhage." 7 Do you see that? 8 A Yes. 9 Q All right. 10 Are either of these gentlemen, Khan or 11 ElSohly, clinicians, to your knowledge? 12 MR. SCOTT: Object as to form. 13 THE WITNESS: They're not 14 clinicians. I didn't know you needed to be 15 to cite a study. 16 BY MR. WENIK: 17 Q Do you consider them experts on the 18 safety of natural products? 19 MR. SCOTT: Same objection. 20 THE WITNESS: They're not -- that's 21 not their area of expertise. However, they 22 certainly can cite things that are in the 23 literature as scientists. 24 MR. WENIK: Do you consider them 25 qualified to evaluate a case report in the</p>
<p>Page 124</p> <p>1 Daniel Fabricant, Ph.D. 2 same vein that you are? 3 MR. SCOTT: Same objection. Object 4 as to form. 5 THE WITNESS: Again, this is for 6 the purpose of publication. My evaluation of 7 this was for the purpose of upholding the 8 law, so it's a different, different area. I 9 think, you know, what they're writing is all 10 based on what's in the literature. 11 BY MR. WENIK: 12 Q Did you think it was odd that chemists 13 who were publishing a study with chromatograms and 14 analyzing whether something is in a plant or not 15 are commenting about the safety of DMAA? 16 A Well, again, it's more than just 17 chemists here, but on the publication list, no. 18 Again, it's not uncommon, and they're citing the 19 literature. It would be uncommon if they didn't 20 cite the literature. 21 (Exhibit 18 was marked for 22 identification.) 23 BY MR. WENIK: 24 Q So, Doctor, I placed before you a 25 document marked for identification as Fabricant</p>	<p>Page 125</p> <p>1 Daniel Fabricant, Ph.D. 2 Exhibit 18. 3 The top of the document appears to be an 4 email between Mahmoud ElSohly and Ikhlas Khan. 5 The bottom seems to be the press release that was 6 in email form that we have in Exhibit 14. 7 Do you see that? 8 A No, they're not the same documents, but 9 that's fine, because obviously this and this are 10 different, how they're formatted, the text. 11 Q That was going to be my next question. 12 Did you forward to them some version of the press 13 release? And you are correct; it is formatted a 14 little differently. That was going to be my next 15 question. 16 A It's computer formatted differently. 17 This we sent around so people were aware of it. 18 Q Okay. Did he call you to congratulate 19 you on the issuance of the warning letters and the 20 press release? Did Dr. ElSohly call you? 21 A I don't think he did, but I heard from 22 Khan. 23 Q And what did Khan tell you? 24 A I think he was, you know -- he was 25 happy, he was supportive, but . . .</p>

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1 Daniel Fabricant, Ph.D.
 2 Q Did both of these gentlemen express to
 3 you their personal view -- well, let's take them
 4 one at a time. I don't want it to be a compound
 5 question.
 6 Did ElSohly express to you -- you
 7 personally, not the FDA as a whole -- express to
 8 you his belief that he thought DMAA was dangerous?
 9 MR. SCOTT: Object as to form.
 10 Time frame.
 11 BY MR. WENIK:
 12 Q At any time.
 13 A Again, people had a lot of different
 14 opinions on it. Dr. ElSohly's opinion and
 15 Dr. Khan's opinion were largely very informative
 16 on the presence of DMAA in geranium. So what
 17 people may have thought otherwise? Okay, people
 18 have opinions. We still have a process, and it's
 19 still -- the agency has to be accountable, so I
 20 guess I don't know the relevance of anyone's
 21 opinion other than the work the agency put into
 22 work the process and be effective regulators.
 23 Q Putting your view as to relevance aside,
 24 did Dr. ElSohly express to you ever his personal
 25 belief that he thought DMAA was dangerous?

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1 Daniel Fabricant, Ph.D.
 2 ever taken.
 3 Q Do you recall whether Dr. ElSohly
 4 expressed to you at any time that his belief that
 5 DMAA should be removed from the marketplace?
 6 A Again, I -- their opinion was valuable
 7 in the presence of DMAA in a plant. That's what I
 8 remember speaking with them about.
 9 Q So would it be fair to say that
 10 Dr. Khan's opinion expressed to you was that DMAA
 11 was not in geraniums?
 12 A The opinion and the science. I mean if
 13 there's a time you want to talk about it, yeah,
 14 because obviously they did a study, and that's
 15 going to shape his opinion on whether or not it's
 16 in there.
 17 Q Did he express to you that opinion in
 18 2012 after he prepared this study that we've
 19 marked as Exhibit 17?
 20 A I think looking at the literature, it
 21 was long before 2012 that we started to discuss
 22 whether or not it was present.
 23 Q And his view was that it was not?
 24 A Well, again, looking at the science,
 25 yeah, his view was that, you know, looking at the

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1 Daniel Fabricant, Ph.D.
 2 MR. SCOTT: Object as to form.
 3 THE WITNESS: Again, I'm not going
 4 to speculate. I'm sure he did. I heard a
 5 lot of different things on DMAA from a lot of
 6 different people.
 7 BY MR. WENIK:
 8 Q Did Dr. Khan express to you at any time
 9 his personal belief that DMAA was dangerous?
 10 MR. SCOTT: Same objection.
 11 THE WITNESS: Same answer. They
 12 might have. Again, it's not really relevant.
 13 BY MR. WENIK:
 14 Q Okay. Did Dr. Khan express to you his
 15 belief that DMAA should be removed from the
 16 marketplace?
 17 A It's not relevant. That's not his
 18 decision to make.
 19 Q I understand that. However, did he
 20 express that belief to you?
 21 A Again, a lot of -- people said a lot of
 22 different things on DMAA. As to specific
 23 conversations, I, I mean there's nothing I can
 24 really say. Just speculate. I can't remember
 25 every conversation I had on every action we've

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1 Daniel Fabricant, Ph.D.
 2 science, it was very, very odd, as someone who has
 3 a natural products background as well, you
 4 generally won't have a plant that's that well
 5 studied that all of a sudden there's a new
 6 compound that no one has seen before, and that
 7 it's there in exactly equal parts four times over,
 8 so yeah, I think those things struck him as odd,
 9 but you'll have to ask him about that.
 10 Q How about Dr. ElSohly; did he express to
 11 you the view around the time of before the
 12 publication of Fabricant Exhibit 17 that he didn't
 13 believe DMAA was in geraniums?
 14 A Before we discussed it, University of
 15 Mississippi was the center of excellence for the
 16 agency, so on ideas relating to botanicals and
 17 botanicals being the subject of regulatory action,
 18 I made use of the center of excellence and
 19 consulted their opinions on some things in
 20 addition to the FDA internal opinions.
 21 Q And was Dr. ElSohly's opinion like
 22 Dr. Khan's you've described, even before
 23 publishing this study, that DMAA was not in
 24 geraniums?
 25 A Again, his opinion -- and you need to

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1 Daniel Fabricant, Ph.D.
 2 ask him -- was based on what he had seen in the
 3 literature and so forth and the oddities there,
 4 that it raised more questions than it answered.
 5 Q And was his belief that it was unlikely
 6 that DMAA was in geraniums?
 7 A I'm not going to speculate to his
 8 belief.
 9 Q Well, what did he say to you?
 10 A Well, what he said to me was based on
 11 what we had seen in the science. There were a lot
 12 more questions than there were answers.
 13 Q And was his view expressed to you that
 14 the science pointed to DMAA not being in
 15 geraniums?
 16 A I think that that was his view, yes.
 17 MR. WENIK: Why don't we take a
 18 break for lunch?
 19 MR. SCOTT: Sure.
 20 (Whereupon, the lunch recess was
 21 taken.)
 22 (Exhibit 19 was marked for
 23 identification.)
 24 BY MR. WENIK:
 25 Q Doctor, I placed before you a document

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1 Daniel Fabricant, Ph.D.
 2 companies?
 3 A I mean I think he was happy. A lot of
 4 people were happy, because it -- you know, again,
 5 the burden -- what people see externally at the
 6 agency is one thing. The work that goes into
 7 making a case and things like that is quite
 8 another. So I think Dr. Khan was happy that the
 9 agency had taken action. You know, I think there
 10 was a lot of people that shared that sentiment,
 11 that there's -- it was odd that DMAA was even
 12 supposed to be there.
 13 Q All right.
 14 (Exhibit 20 was marked for
 15 identification.)
 16 BY MR. WENIK:
 17 Q So I have another email chain or rather
 18 extension of the email chain that began here in
 19 Fabricant Exhibit 19 with a couple more emails in
 20 Fabricant Exhibit 20.
 21 I guess my first question is: Are you
 22 in the email chain that we have identified here in
 23 Fabricant Exhibit 20? Does your name appear?
 24 A Yes.
 25 Q And it's an exchange between you and

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1 Daniel Fabricant, Ph.D.
 2 that I've marked for identification as Fabricant
 3 Exhibit 19, which is -- there's an email from
 4 Dr. Khan to you at the top of April 30th,
 5 forwarding an AHPA update.
 6 Do you see that?
 7 A Yes.
 8 Q Have you seen this document before?
 9 A Yes.
 10 Q What is the AHPA?
 11 A American Herbal Products Association.
 12 Q And what relationship, if any, does that
 13 entity have with the NPA?
 14 A Just another trade association.
 15 Q And if we note the date, it's April 30,
 16 which is shortly after the press release we had
 17 identified as Fabricant Exhibit 13, and so the
 18 press release I take it generated some news
 19 coverage in various period publications; is that
 20 right?
 21 A Yes. Anytime the agency does anything,
 22 it's a public agency.
 23 Q Okay, and did this spark any
 24 conversation between you and Dr. Khan regarding
 25 the action that was taken against these various

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1 Daniel Fabricant, Ph.D.
 2 Dr. Khan where you said, "As Norm used to say',
 3 Never underestimate the predictability of
 4 stupidity."
 5 Who is Norm? Who are you referring to?
 6 A My Ph.D. advisor, but he is no longer
 7 with us. Norm Farnsworth.
 8 Q And you wrote, "It's amazing that folks
 9 can still say it's in the plant."
 10 By "in the plant," were you referring to
 11 geranium?
 12 A Yes. I think, you know, it was from
 13 a -- we were excited at the agency about
 14 protecting public health. You had something here
 15 that was put forth that it was very, it was very
 16 concerning.
 17 Q All right. Take a look at the second
 18 page of this document if you don't mind, Fabricant
 19 Exhibit 20.
 20 A Sure.
 21 Q So there's this blurb again from the
 22 AHPA, and look at the third full paragraph, the
 23 last sentence. "In AHPA's views, if DMAA exists
 24 in geranium through the plant's own synthesis
 25 processes, human-synthesized DMAA is also a lawful

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<p>1 Daniel Fabricant, Ph.D. 2 dietary ingredient." 3 Is that a proposition that you disagree 4 with? 5 MR. SCOTT: Object as to form. 6 THE WITNESS: I'm sorry. Would you 7 point out where -- 8 BY MR. WENIK: 9 Q I'm looking at the third full paragraph, 10 the very last sentence. It says, "In AHPA's view, 11 if DMAA exists in geranium through the plant's own 12 synthesis processes, human-synthesized DMAA is 13 also a lawful dietary ingredient." 14 My question is whether you disagree with 15 that, that proposition. 16 A Well, there's two propositions in that 17 statement. Which one are you asking if I disagree 18 with; if DMAA is in the plant or if 19 human-synthesized DMAA is also a lawful 20 ingredient? 21 Q Well, let's take the last one. Is 22 human-synthesized DMAA a lawful dietary 23 ingredient? 24 A That would not be the agency's position, 25 no.</p>	<p>1 Daniel Fabricant, Ph.D. 2 Q Okay, and I take it even if it existed 3 in the plant, that would be your position? 4 A Well, again, I think that when you're 5 dealing with synthesis of a botanical, there are 6 certain factors that need to be considered, so I 7 don't think that this accurately -- this statement 8 accurately captures that. 9 Q What other things need to be considered, 10 in your opinion? 11 A Well, the agency just released a new 12 guidance, draft guidance on NDIs where they talk 13 about chirality and they talk about things like 14 that. So just because it's synthesized wouldn't 15 make it lawful. Other things would have to be 16 considered appropriately. 17 (Exhibit 21 was marked for 18 identification.) 19 BY MR. WENIK: 20 Q Dr. Fabricant, I've placed before you a 21 document that I've marked for identification as 22 Fabricant Exhibit 21, and let me put an 23 explanation on the record. 24 The first page has a Bates number of 25 GOV-007039. The document that's attached to it</p>
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<p>1 Daniel Fabricant, Ph.D. 2 has a different Bates numbering system. I'll 3 represent to you that the government did not 4 produce the attachments to emails to us 5 sequentially documented, but we were able to 6 determine from the metadata and the families which 7 went with which. 8 So I'll represent to you that it's my 9 belief that the document that begins GOV-012486 is 10 the attachment that's identified in the document 11 that belongs to Fabricant Exhibit 21. 12 A Okay. 13 Q At any rate, we talked before, I think, 14 about -- I think you mentioned in passing Frank 15 Jaksch, and he is a founder of ChromaDex; is that 16 right? 17 A That's correct. 18 Q All right, and he sent you -- do you 19 recall him sending you, back in August of 2012, 20 the Li study that purported to find DMAA in 21 geranium? 22 A Do I remember it, no, but obviously it 23 happened. It's right here, and I'm pretty sure we 24 had it before he sent it to us. 25 Q Okay, and do you recall whether you</p>	<p>1 Daniel Fabricant, Ph.D. 2 reviewed this study at the time it came in to the 3 FDA sometime in 2012? 4 A When it came in, yeah, of course, we 5 reviewed it. 6 Q Okay, and what reaction did you have 7 when you saw the study, the best you can recall? 8 I understand we're talking four years later. What 9 was, best you recall, your initial reaction to it 10 when you first saw that study? 11 MR. SCOTT: Let me stop and impose 12 an objection. 13 You can answer the question to the 14 extent that it relates to any positions that 15 you have taken public or the agency has taken 16 public, but if there are conversations, 17 analysis that went on before there being a 18 public position regarding the study and how 19 it goes into your analysis, you should not 20 reveal those, because those are part of the 21 deliberative process privilege. 22 THE WITNESS: Yeah, I think we -- 23 there's really nothing to say. 24 BY MR. WENIK: 25 Q Does this spark a conversation that you</p>

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<p>1 Daniel Fabricant, Ph.D. 2 had with Dr. Khan after you saw this paper? 3 A Yes. 4 Q Let me show you this. 5 (Exhibit 22 was marked for 6 identification.) 7 BY MR. WENIK: 8 Q So I've just placed before you Fabricant 9 Exhibit 22, which is an August 8th email from 10 Dr. Khan to you, which simply states, "I'm sure 11 you saw the DMAA paper. I think you should get 12 fresh material which they received from China and 13 analyze to find all isomers." 14 So I'm looking at the other document, 15 Fabricant Exhibit 21, which is also dated 16 August 8, so let me just, now that I've placed 17 this in front of you, first of all, does Fabricant 18 Exhibit 22 have your name in the email chain? 19 A Yes. 20 Q And looking at this, does this refer to 21 the Li paper that was seen in Fabricant Exhibit 22 21, the other DMAA paper? 23 MR. SCOTT: Exhibit 22. 24 BY MR. WENIK: 25 Q Right.</p>	<p>1 Daniel Fabricant, Ph.D. 2 A I believe it does. 3 Q All right, and -- 4 A I didn't write the email, so . . . 5 Q Right. What is your recollection of 6 what conversation was sparked when Dr. Khan 7 emailed you about this paper, saying that you 8 should get fresh material? 9 A Well, I think when we saw the paper, we 10 knew what our burden would be at the agency in 11 terms of, in terms of moving ahead. 12 Q And what was that burden? 13 A Well, I think that, you know, we had -- 14 USP continued to provide some science. We 15 certainly felt very good about our scientific 16 base, but we anticipated that there may possibly 17 be a question about, okay, what about this study, 18 and so we repeat it. Generally that's what you do 19 if you get an outlier result. You find a way to 20 substantiate it. 21 So this was an outlier result, and so 22 you don't just publish this and go "okay, that's 23 it, it's done" for something that's never been 24 seen before in a plant that was extensively 25 studied for -- I mean the economic impact of rose</p>
<p>Page 140</p> <p>1 Daniel Fabricant, Ph.D. 2 geranium oil, 50, 75 years, it was extensively 3 studied. The plant had been effectively ripped 4 apart by phytochemists and every component 5 isolated, so when people show up and go, "oh, 6 yeah, we found it, hey, accept it," that's 7 generally not how it works. You generally need 8 confirmation, and so that was the discussion. 9 Q And did you discuss with Dr. Khan about 10 having the center down in University of 11 Mississippi do a follow-up study? 12 A Yes. 13 Q Having read the Li paper at the time, 14 did that raise a question in your mind whether 15 geraniums might actually have DMAA in them? 16 A I -- you know, I only comment on this 17 paper and the memo and some of the challenges with 18 it, so I'll stand on that. 19 Q All right. 20 (Exhibit 23 was marked for 21 identification.) 22 (Exhibit 24 was marked for 23 identification.) 24 BY MR. WENIK: 25 Q Have you had a moment to look at what</p>	<p>Page 141</p> <p>1 Daniel Fabricant, Ph.D. 2 I've marked as Fabricant Exhibit 23 and Fabricant 3 Exhibit 24, Doctor? 4 A Yes. 5 Q All right. Looking at Fabricant Exhibit 6 23 first, is your name in the email chain at the 7 top from Ikhlas Khan to you? 8 A Yes. That's the only place it is. 9 Q All right. It looks like Dr. Khan 10 forwarded to you an email he had received -- I'm 11 sure I'll pronounce this wrong -- from 12 Zhangwei-dong. 13 Do you know who Zhangwei-dong is? 14 A Yeah, they're part of Khan's network in 15 China. They help get, they help get plant 16 material. 17 Q Okay, and Zhangwei-dong had outlined to 18 Dr. Khan -- it says, "Dear Ik, I got your problem 19 in MHA analysis of natural-derived samples. I 20 agree with you that it's an essential and 21 important question to make sure whether natural 22 materials contain detectable qualities of MHA, and 23 I'm glad to help you as much as we can in the 24 first time. We could do the work as following," 25 and then he talks about collecting samples.</p>

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<p>1 Daniel Fabricant, Ph.D. 2 Do you see that? 3 A Yes. 4 Q All right, and Dr. Khan asked, "What do 5 you think about this strategy?" 6 A Yes. 7 Q And was this email exchange part of what 8 you just referred to before, that in the wake of 9 the Li paper, you were talking about doing another 10 study with the University of Mississippi; is that 11 right? 12 A Yes. 13 Q Okay, and we have this other email here, 14 Fabricant Exhibit 24, an August 9, 2012 email from 15 you to Dr. Khan. 16 Do you see that? 17 A Yes. 18 Q Okay, and you said "I like it." Is that 19 "I like it" responding to the strategy that's 20 outlined below in the other emails? 21 A Yes. 22 Q And you wrote, "The other issue is look 23 at that waters system, it's older than waters." 24 What is that referring to, looking at the waters 25 system?</p>	<p>1 Daniel Fabricant, Ph.D. 2 A It's the HPLC system. 3 Q So that means you were concerned about 4 the testing methodology that was used in the Li 5 paper? 6 A Yes. 7 Q Okay, and then you wrote, "Plus I don't 8 think that LOD is real." 9 Does "LOD" stand for "level of 10 detection"? 11 A Limit of detection. 12 Q Okay, and were you saying that you 13 didn't think that the limit of detection was real 14 in the Li paper? Is that what you were referring 15 to? 16 A Consulting with my chemists, they raised 17 a flag on that, that it seemed very odd, the 18 concentrations that were there, the ranges. 19 Q All right, and was there, in the wake of 20 these communications, a multi-centre study of 21 geraniums that was, for lack of a better word, 22 "quarterbacked" by Dr. ElSohly and Dr. Khan at the 23 University of Mississippi? 24 A Well, they -- I mean they were getting 25 plant material. Multi-centre, I don't --</p>
Page 144	Page 145
<p>1 Daniel Fabricant, Ph.D. 2 Q Well, let me show you the argument. 3 It's not a memory quiz. 4 (Exhibit 25 was marked for 5 identification.) 6 BY MR. WENIK: 7 Q I've marked for identification 8 Fabricant Exhibit 25, which is an article offered 9 by Dr. ElSohly, Dr. Khan, and others that came out 10 in August of 2014, I think right after you left 11 the FDA. And if you look at the abstract, it 12 talks about them using -- I call it multi-centre. 13 They talk about using four different sites for 14 analysis of geranium samples, I suppose. 15 Does this -- Fabricant Exhibit 25, is 16 this publication a culmination of the new testing 17 and research that we were talking about early on 18 that eventually took place? 19 A Well, I mean if this was -- this is an 20 extension of this work and getting those samples 21 and evaluating, reevaluating it. 22 Q So the samples we're talking about in 23 Fabricant Exhibit 24 and Fabricant Exhibit 25, 24 that strategy ultimately culminated in the study 25 we have as Fabricant Exhibit 25?</p>	<p>1 Daniel Fabricant, Ph.D. 2 A That would be what I would think. 3 Obviously, there were other samples, too. 4 Q Right. I understand. 5 So let me show you another couple of 6 documents. 7 (Exhibit 26 was marked for 8 identification.) 9 (Exhibit 27 was marked for 10 identification.) 11 BY MR. WENIK: 12 Q So, Doctor, I've placed before you what 13 I've marked for identification as Fabricant 14 Exhibit 26, which is an email chain between you 15 and Vincent Bunning and some others, and which -- 16 looks like it encloses an article, a news account. 17 A Mm-hmm. 18 Q Is that right? 19 A Yes. 20 Q All right, and your name is in the email 21 chain? 22 A Yes. 23 Q And I take it you've seen this before, 24 this email chain? 25 A I have.</p>

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<p>1 Daniel Fabricant, Ph.D. 2 Q And then I marked as Fabricant Exhibit 3 27 a study by Fleming, talking about an analysis 4 and confirmation of DMAA. 5 Do you see that? 6 A Yes. 7 Q All right. So turning to Fabricant 8 Exhibit 26, the article that's in the email by 9 Stephen Daniells, dated December 3, 2012, talking 10 about the study -- he talks about a study 11 published in Analytical Chemistry Insights. 12 Is that -- is he referring -- is it your 13 understanding, looking at this, that he's 14 referring to what I've marked as Fabricant Exhibit 15 27? 16 A Yes. 17 Q All right, and do you believe that you 18 had seen the study that I've marked as Fabricant 19 Exhibit 27 back in December of 2012 around when it 20 first came out? 21 A Mm-hmm, yes. 22 Q Okay, and you have some email exchange 23 here between some individuals. I'd like to first 24 go through who they are. 25 Who is Vincent Bunning?</p>	<p>1 Daniel Fabricant, Ph.D. 2 A He was the deputy director for the 3 Office of Regulatory Science. 4 Q All right. I think you mentioned Steven 5 Musser earlier. Was he a -- 6 A At that point he was just the office 7 director. 8 Q And then we've already talked about 9 Mr. Hilmas. 10 So then we have Jeanne Rader. Who is 11 that person? 12 A She was the division director in that 13 office. 14 Q And the article talks about some 15 findings made in Fabricant Exhibit 27, and you 16 wrote an email to these individuals saying "pretty 17 ridiculous." 18 What was your, the basis for your 19 thinking that the findings were "pretty" -- well, 20 let me step back. 21 When you said something was "pretty 22 ridiculous," did you think the findings in the 23 study were pretty ridiculous or the fact that the 24 study had been done? 25 MR. SCOTT: Object as to form.</p>
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<p>1 Daniel Fabricant, Ph.D. 2 THE WITNESS: This is all covered 3 in the memo. There are a lot of questions 4 with this study and the supposition that -- 5 it was seemingly only found from the 6 company's research, that all these other 7 experts in botanicals couldn't find it, but 8 yet it just kept showing up again and again 9 and again. There was no biosynthetic 10 pathway. There was nothing that made it 11 clear that it was even possible; yet it just 12 kept showing up in the company's research 13 which wasn't even peer-reviewed. 14 So yeah, I think in terms of 15 protecting the public health, it seemed kind 16 of ridiculous. 17 BY MR. WENIK: 18 Q And so for "the company," I think you're 19 referring to USPlabs, is that correct, that they 20 were the ones that sponsored these studies? 21 A Yes. 22 Q All right, and you don't believe that 23 this journal Analytical Chemistry Insights is a 24 peer-reviewed journal? 25 A It's not. It's an open-access journal.</p>	<p>1 Daniel Fabricant, Ph.D. 2 Q So I take it you had some questions 3 about the validity of this research that's 4 reflected in Fabricant Exhibit 27? 5 A I think that's clear in our letter back 6 to USPlabs. 7 Q Let me ask you this. You mentioned 8 that, the concern about it, having seen it in 9 studies sponsored by USPlabs. Would your view -- 10 would you have had less questions if the research 11 had been done by an objective, neutral third 12 party? 13 A I can't say. It's speculation. What I 14 can say is when you -- and as we pointed out, you 15 have these questions that remain unanswered, and 16 they were only showing up, again, positively in 17 the company's research in non-peer-reviewed 18 journals. It wouldn't be hard for the company to 19 approach a botanical expert and say "what do I 20 need to do to substantiate this finding." That 21 would be what a responsible company would do. At 22 no point in time was that made evident. 23 Q Let me ask you this: So in your 24 conversations with Drs. Khan and ElSohly leading 25 up to the research that culminated in Fabricant</p>

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1 Daniel Fabricant, Ph.D.
 2 Exhibit 25, did you give them any goal that you
 3 wanted them to achieve, such as disproving that
 4 DMAA was in geraniums?
 5 A I didn't think it was there, but the
 6 science is going to be the science. I wanted them
 7 to do the science. The science will ultimately
 8 tell the tale. I knew they did good science.
 9 Q So you didn't -- would it be fair to say
 10 you didn't give them marching orders about what
 11 findings you wanted them to come up with or
 12 anything like that?
 13 A No. I wanted the science done.
 14 (Exhibit 28 was marked for
 15 identification.)
 16 BY MR. WENIK:
 17 Q Doctor, I've placed before you a
 18 document I've marked as Fabricant Exhibit 28,
 19 which for the record is a download of a posting on
 20 the FDA's website, and it's entitled "Stimulant
 21 Potentially Dangerous to Health, FDA Warns."
 22 If you'd take a moment to look at this,
 23 my first question to you is whether you recognize
 24 this warning, this warning document.
 25 A Yes, I do. It's a consumer update.

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1 Daniel Fabricant, Ph.D.
 2 A I think the goal was to protect
 3 consumers and public health.
 4 Q All right, and part of doing that would
 5 be to remove DMAA from the marketplace?
 6 A Part of that, yes.
 7 Q Okay, and if you look at the second
 8 paragraph down, it says, "As of April 11, 2013,
 9 FDA had received 86 reports" --
 10 MR. SCOTT: You said the second
 11 paragraph?
 12 MR. WENIK: I'm sorry. You're
 13 right. Third paragraph.
 14 BY MR. WENIK:
 15 Q "As of April 11, 2013, FDA had received
 16 86 reports of illnesses and deaths associated with
 17 the supplement containing DMAA."
 18 Do you see that?
 19 A Yes.
 20 Q Now, turn to the second page of the
 21 document.
 22 A Well, before you do that, the whole
 23 thing is in context there with regard to the
 24 report. You can't just take that sentence out of
 25 context. I think, you know, with adverse event

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1 Daniel Fabricant, Ph.D.
 2 Q All right, and did you draft this
 3 consumer update?
 4 A I worked with the Office of Public
 5 Affairs to draft it, yes. I wasn't the only one.
 6 Q All right, and whose decision was it to
 7 post it on the FDA website?
 8 A The commissioner of the Office of Foods,
 9 Mike Taylor.
 10 Q Did you agree with the posting of this
 11 on the FDA's website?
 12 A I did.
 13 Q All right. So I'm looking at the first
 14 page, and it says that "the Food & Drug
 15 Administration is using all available tools at its
 16 disposal to ensure that dietary supplements
 17 containing a stimulant called dimethylamylamine
 18 (DMAA) are no longer distributed and available for
 19 sale to consumers in the marketplace."
 20 Do you see that?
 21 A Yes.
 22 Q Would it be fair to say that the goal of
 23 the FDA, at least at the point in time when this
 24 was drafted, was to remove DMAA from the
 25 marketplace?

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1 Daniel Fabricant, Ph.D.
 2 reports, it's important that all of that
 3 information is there.
 4 Q All right. I was just candidly asking
 5 you about just do you accept the date of when this
 6 was created, because it says here that --
 7 obviously, this was created at least on April 11,
 8 2013, and then the next page I'm looking --
 9 A Well, it wasn't created on April 11.
 10 That was the last time that, before this went out,
 11 that someone had checked. That was the last date
 12 you could verify the adverse event reports.
 13 Q Right, but I'm saying that the posting
 14 and finalization of this document -- so I'm
 15 looking there. So you said you had some data as
 16 of April 11, 2013, and I'm looking at the next
 17 page, the first column, the first full paragraph.
 18 You're talking about, in this update,
 19 "However, after reviewing the studies provided by
 20 USPlabs, FDA has found the information
 21 insufficient to defend the use of DMAA as an
 22 ingredient in dietary supplements. FDA is
 23 finalizing a formal response to the firm to
 24 reflect its findings, according to Daniel
 25 Fabricant, Ph.D.," and the final -- the formal

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1 Daniel Fabricant, Ph.D.
 2 response, I assume, was Fabricant Exhibit 6,
 3 correct?
 4 A Yes.
 5 Q All right. So would you agree with me
 6 that means that this document must have been
 7 posted and created sometime, or finalized I guess
 8 is the better way to say it, sometime between
 9 April 11 and April 18 when this was finalized?
 10 A Again, without the date there -- I'm not
 11 going to pretend to remember what happened between
 12 April 11 and April 18, to the exact, you
 13 know . . .
 14 Q All right, and you wrote here in the
 15 second column on the second page --
 16 A I wasn't the only author here.
 17 Q No, but this actually quotes you. It
 18 says, "Consumers" -- I'm looking at the third full
 19 paragraph. "'Consumers may mistakenly looking at
 20 a capsule and think that FDA has signed off on
 21 that product as safe and effective prior to that
 22 product appearing on the market, as we do with
 23 drugs and other medical products,' says Fabricant.
 24 'In contrast, with dietary supplements, there is
 25 no premarket approval, and once a product is on

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1 Daniel Fabricant, Ph.D.
 2 sense of urgency?
 3 A I don't know that that's the case, and
 4 you don't know if that's the case either. It
 5 might have been this was written probably leading
 6 up to this, but in terms of a posting date, unless
 7 you have a posting date, I'm really not going to
 8 answer that question.
 9 Q Well, if it was posted after that
 10 letter, then this would be inaccurate, right, in
 11 the sense that you're finalizing a formal
 12 response?
 13 A It could have been posted after. Again,
 14 the timeline here is . . .
 15 Q All right. Do you do consumer updates
 16 for all of FDA's case?
 17 A For a lot of them.
 18 Q Was there any particular reason why this
 19 one was selected to have a consumer update?
 20 A It's a public health agency. This was
 21 something that was out there in the public health
 22 that was a large selling product that a lot of
 23 people used.
 24 Q Do you know who designed the graphic on
 25 the first page with the words "Heart Attack" in

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1 Daniel Fabricant, Ph.D.
 2 the market, the burden is on the FDA to prove that
 3 the product is unsafe."
 4 Do you see that?
 5 A Yes.
 6 Q All right, and do you believe that to be
 7 true?
 8 MR. SCOTT: Object as to form.
 9 THE WITNESS: For products that are
 10 legitimately dietary supplements, yes.
 11 BY MR. WENIK:
 12 Q Okay.
 13 A Again, that product has to be lawful.
 14 It probably should say "with lawful dietary
 15 supplements, there is no premarket approval."
 16 That's important.
 17 Q Okay. My question is -- so this
 18 document was posted, and I understand you don't
 19 want to be boxed into an exact date, and that's
 20 fair, but it's clear that you refer to that the
 21 formal response had not been finalized yet to the
 22 USPlabs submission.
 23 So my question simply is: What was the
 24 reasoning to have this posted on the FDA website
 25 before that response was finalized? What was the

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1 Daniel Fabricant, Ph.D.
 2 bold?
 3 A The Office of Public Affairs.
 4 (Exhibit 29 was marked for
 5 identification.)
 6 BY MR. WENIK:
 7 Q Dr. Fabricant, I placed before you an
 8 email with an attached article from a Brian Somers
 9 to you, dated March 17, 2013.
 10 My first question is: Do you recognize
 11 having seen this before?
 12 A Let me go through it.
 13 Q Sure, please.
 14 (Witness peruses document.)
 15 THE WITNESS: Okay.
 16 BY MR. WENIK:
 17 Q Have you seen this before, what we've
 18 marked as Fabricant Exhibit 29?
 19 A I believe I have.
 20 Q All right. Who is Brian Somers?
 21 A He worked for the Office of Nutrition,
 22 Labeling, and Dietary Supplements.
 23 Q So he was one of your subordinates when
 24 you were at the FDA?
 25 A He eventually became one, but not during

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1 Daniel Fabricant, Ph.D.
 2 this time period.
 3 Q All right.
 4 A He was in another, another part of the
 5 office.
 6 Q All right. Do you recall being
 7 interviewed for an article by the New York Times
 8 about DMAA?
 9 A I was interviewed a lot of times by the
 10 New York Times for a variety of things. DMAA was
 11 one of the topics.
 12 Q My question is: Having looked at this
 13 article, this New York Times article that we've
 14 marked here as Fabricant Exhibit 29, do you recall
 15 whether that article was one of the reasons that
 16 the agency put out Exhibit 28, that consumer
 17 update, having seen this article?
 18 A Again, that was the Office of Public
 19 Affairs and the Commissioner for Foods that were
 20 in charge of putting these out, so I supported
 21 putting that out. As to their decision-making and
 22 what role this had, you'd have to ask them that.
 23 Q Okay. Fair enough.
 24 Were you involved at all in a consulting
 25 capacity in anything in the litigation that

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1 Daniel Fabricant, Ph.D.
 2 6?
 3 A Yes. In the "to" line, it's to the
 4 Division of Enforcement. There I believe were
 5 other documents as well.
 6 Q And would it be fair to say that the
 7 analysis that Ms. Thomas set forth in this letter
 8 that you agree with that analysis in Fabricant
 9 Exhibit 6?
 10 A Yes. I mean we continued to work
 11 together on the letter as it was being developed.
 12 MR. SCOTT: Let's take a break for
 13 a minute.
 14 MR. WENIK: Sure.
 15 (Whereupon, a short recess was
 16 taken.)
 17 (Exhibit 31 was marked for
 18 identification.)
 19 BY MR. WENIK:
 20 Q Doctor, I've placed before you a
 21 document that I've marked for identification as
 22 Fabricant Exhibit 31, which for the record is a
 23 printout from the US Food and Drug Administration
 24 website, dated July 16, 2013, and it's a Q&A about
 25 DMAA.

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1 Daniel Fabricant, Ph.D.
 2 Michael Sparling, the soldier who is the subject
 3 of this article, brought against USPlabs?
 4 A No.
 5 Q Had you been following at all the
 6 results of that litigation?
 7 A No.
 8 (Exhibit 30 was marked for
 9 identification.)
 10 BY MR. WENIK:
 11 Q Doctor, I've placed before you a
 12 document I marked for identification as Fabricant
 13 Exhibit 30, which is a February 9, 2013 memorandum
 14 authored by you, and please take a moment to look
 15 at that. My first question is whether you
 16 recognize the document.
 17 (Witness peruses document.)
 18 THE WITNESS: Yes.
 19 BY MR. WENIK:
 20 Q So looking at this document, you
 21 referred before that some memoranda may have been
 22 prepared prior to Fabricant Exhibit 6 going out.
 23 Is this document, Fabricant Exhibit 30,
 24 a memo that you shared with Jennifer Thomas for
 25 her to use in helping to craft Fabricant Exhibit

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1 Daniel Fabricant, Ph.D.
 2 A Mm-hmm.
 3 Q So my question to you is: Have you seen
 4 this before, this Q&A about DMAA?
 5 A Yes.
 6 Q Did you draft this Q&A, or --
 7 A I worked with our Office of Public
 8 Affairs and the attorneys.
 9 Q All right, and the questions and
 10 answers, you feel that they're accurate?
 11 Let me rephrase that. You feel the
 12 information provided in the answers to the
 13 questions are accurate?
 14 A Yes. I mean, you know, so long as it's
 15 taken in the proper context, yeah, everything is
 16 right on.
 17 Q All right. In the first sentence where
 18 it says "What is DMAA," it says, "DMAA is an
 19 amphetamine derivative."
 20 What was the basis to your
 21 understanding -- factual basis for asserting that
 22 DMAA is an amphetamine derivative?
 23 A Well, that was language that they wanted
 24 to use to warn people. Again, we do know it
 25 behaves like an amphetamine, so I think that that

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1 Daniel Fabricant, Ph.D.
 2 was thinking on that one.
 3 Q Did Dr. Cohen, Pieter Cohen suggest
 4 using that language to you?
 5 A No.
 6 Q And I'm looking at a block here that
 7 says "How does FDA regulate ingredients in dietary
 8 supplements like DMAA," and in the fourth line
 9 from the bottom, it says, "However, in order for
 10 FDA to ban a compound in a dietary supplement, FDA
 11 is required under the statute to undertake a
 12 series of lengthy scientific and legal steps."
 13 What's your understanding of what this
 14 series of lengthy scientific and legal steps are
 15 that are required to ban a dietary supplement?
 16 A Dietary ingredient. They would be the
 17 same that were taken in ephedra, but that supposes
 18 first that it's an actual dietary ingredient.
 19 With DMAA, that wasn't the case, wasn't the
 20 ultimate rendering.
 21 Q Okay.
 22 A That is important. You can't ban
 23 something that's not a dietary ingredient.
 24 (Exhibit 32 was marked for
 25 identification.)

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1 Daniel Fabricant, Ph.D.
 2 between them and the agency was and what some of
 3 the hot topics were, if you will, so I was just
 4 sending him some articles that were out there.
 5 Q Okay. Was he providing you updates
 6 about, as we discussed earlier, oh, maybe a half
 7 hour ago, that they were going to do some more
 8 research on DMAA and geraniums? Were they giving
 9 you updates on the progress of that research that
 10 they were doing?
 11 A We talked about it. We talked that it
 12 was ongoing.
 13 (Exhibit 33 was marked for
 14 identification.)
 15 BY MR. WENIK:
 16 Q Doctor, I've placed before you a
 17 document that I marked for identification as
 18 Fabricant Exhibit 33, which is a copy of an
 19 article from the Atlanta Journal-Constitution from
 20 November 2, 2013. If you could take a couple of
 21 minutes to read through the article, I want to ask
 22 you a couple questions about this.
 23 (Witness peruses document.)
 24 THE WITNESS: Okay.
 25

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q Dr. Fabricant, I've placed before you a
 4 document I marked for identification as Fabricant
 5 Exhibit 32, which is an email between you and
 6 Ikhlas Khan and Troy Smillie.
 7 A Smillie.
 8 Q Have you seen this before?
 9 A Yes.
 10 Q Who is Troy Smillie?
 11 A He used to work with Ikhlas Khan at
 12 University of Mississippi.
 13 Q Is he a scientist of some sort?
 14 A He is a Ph.D.
 15 Q Is his area of expertise chemistry as
 16 well?
 17 A His degree is in pharmacognosy.
 18 Q All right, and I notice here there are
 19 some links to stories about DMAA that you emailed
 20 to Dr. Khan; is that right?
 21 A Yes, as they had to -- you know, they
 22 have to report on their activities, and so we had
 23 some conversations about that they had the new
 24 stories that were out there on it in terms of, you
 25 know, what the, quote-unquote, "interaction"

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1 Daniel Fabricant, Ph.D.
 2 BY MR. WENIK:
 3 Q All right. So having looked at this
 4 article that I placed before you as Fabricant
 5 Exhibit 33, does this refresh any recollection you
 6 might have of having been interviewed by Danny
 7 Robbins of the Atlanta Journal-Constitution a
 8 couple years back?
 9 A I remember talking to Danny.
 10 Q And on page 3 of the article it talks
 11 about this interview, and he wrote, Mr. Robbins
 12 wrote that "the FDA's top supplement official, Dan
 13 Fabricant, acknowledged that the FDA was familiar
 14 with Wheat but wasn't aware his companies were
 15 selling DMAA products until informed by the
 16 newspaper."
 17 Is that accurate, that statement?
 18 A I'm not entirely sure that it is.
 19 Q Okay. After you had this interview with
 20 Mr. Robbins, did you direct an inspection to be
 21 taking place of the facilities of Hi-Tech
 22 Pharmaceuticals in Georgia?
 23 A I believe we worked with -- there was
 24 another issue at the same time we were focused on,
 25 and it's right here in the ingredient, acacia

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1 Daniel Fabricant, Ph.D.
 2 rigidula. It was another NDI we were concerned
 3 with, had gone unfiled and more than likely wasn't
 4 actually a dietary ingredient. So in working with
 5 the district office in Atlanta, we wanted to
 6 inspect the facility.
 7 Q Was the impetus for the inspection the
 8 conversation that took place with this journalist?
 9 A Again, I can't -- that wouldn't have
 10 been the reason. The reason would have been if he
 11 was out there selling DMAA, as the agency had
 12 already taken plenty of action on DMAA, it didn't
 13 matter who it was, that we were going to continue
 14 those efforts to -- you know, it is the agency's
 15 authority to take those products that are
 16 adulterated off the market.
 17 So given that there were seizure actions
 18 already put forth, and one by that district, that
 19 district also handled the seizure that was in
 20 Anderson, South Carolina, the Atlanta district
 21 office. It was -- again, where we saw it, we, we
 22 took the appropriate steps to defend the public
 23 health per our legal authority.
 24 Q Were you aware or -- let me rephrase it.
 25 So before that interview with the

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1 Daniel Fabricant, Ph.D.
 2 onto these inspections at Hi-Tech Pharmaceuticals?
 3 A Didn't have to. They were already
 4 briefed from the GNC case.
 5 Q Did you provide them additional
 6 information about Hi-Tech Pharmaceuticals or
 7 Mr. Wheat?
 8 A Didn't have to. All the documents were
 9 pretty much prepared. They were the exact same
 10 documents we used in the GNC seizure, if memory
 11 serves.
 12 (Exhibit 34 was marked for
 13 identification.)
 14 BY MR. WENIK:
 15 Q Dr. Fabricant, I've placed before you a
 16 document with Bates number GOV-003535 through
 17 GOV-003544. If you'll flip through that for a
 18 minute or two, I want to ask you a couple of
 19 questions.
 20 A Okay.
 21 Q Have you seen these documents before?
 22 A Some of them yes, some of them no.
 23 These are -- these were between ORA, Office of
 24 Regulatory Affairs.
 25 Q Did you know Robin Goins?

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1 Daniel Fabricant, Ph.D.
 2 Atlanta Journal-Constitution journalist, was the
 3 agency aware that Hi-Tech Pharmaceuticals was
 4 selling DMAA-containing products?
 5 A It was -- again, if, if memory serves, I
 6 thought we already had inspectors in there, and
 7 the inspectors had pointed it out because we were
 8 looking at this other issue, but again, it doesn't
 9 really seem to be -- if it's there, we took
 10 appropriate action. It's not a lawful dietary
 11 ingredient.
 12 Q What role, if any, did you have with the
 13 inspections that took place in 2013 at Hi-Tech
 14 Pharmaceuticals?
 15 A It may have been a for-cause inspection,
 16 but I don't know if initially it was a for-cause
 17 inspection, but then it became a for-cause
 18 inspection when we realized there was DMAA at the
 19 facility.
 20 Q And what is a for-cause inspection?
 21 A That means that the inspectors, through
 22 the district, are directed to go out to a facility
 23 and really get a handle on what exactly is the
 24 nature of the issue.
 25 Q Did you brief the inspectors that went

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1 Daniel Fabricant, Ph.D.
 2 A I had spoken with Robin.
 3 Q And I'm looking at the page GOV-003540.
 4 There's an email chain between Robin and some
 5 others at, I assume at FDA, and in the next to the
 6 last paragraph she talks about getting "samples
 7 analyzed as quickly as possible, as we are seeking
 8 serious regulatory action against this firm and
 9 are ready to get these products off the shelf."
 10 Had you given instructions that this
 11 matter was to be expedited or given priority in
 12 some way, this matter against Hi-Tech?
 13 A Well, I mean when there's a product
 14 there that the agency has already acted upon, you
 15 don't really need to tell anyone to step on it.
 16 They were -- you know, you don't see me on that
 17 thread. That looks like them telling them to
 18 expedite it, so that's their words. I mean you
 19 always want to take fast action if it's an
 20 adulterated product. That's kind of the charge of
 21 the agency.
 22 Q Okay. Take a hook at the page that's
 23 marked on the bottom 003541.
 24 A Okay.
 25 Q And the next to the last paragraph talks

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1 Daniel Fabricant, Ph.D.
 2 about: "Due to the urgency of this case and
 3 previous issues with this firm, how soon can we
 4 expect results and is it possible to have the
 5 results as soon as possible?"
 6 Were you aware of previous issues with
 7 Hi-Tech Pharmaceuticals?
 8 A The district certainly was, and as you
 9 can see, I'm not on this. This is from Robin
 10 Goins. I don't --
 11 Q If you don't know, you don't know. If
 12 that's the answer, that's fine.
 13 A We have a record of folks' activities,
 14 and . . .
 15 Q Okay. All right. We're getting near
 16 the end.
 17 (Exhibit 35 was marked for
 18 identification.)
 19 BY MR. WENIK:
 20 Q Okay. So I marked for identification as
 21 Fabricant Exhibit 35 an email chain that has some
 22 emails and some talking points, and my first
 23 question to you is: Do you recall seeing this
 24 document?
 25 A Yes.

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1 Daniel Fabricant, Ph.D.
 2 Q "API," does that stand for "active
 3 pharmaceutical ingredient"?
 4 A It does.
 5 Q And it talks in the email chain about an
 6 interview with NBC News and you to discuss the
 7 history and use of DMAA, and that interview took
 8 place; is that right? You eventually sat down
 9 with him?
 10 A Yes.
 11 (Exhibit 36 was marked for
 12 identification.)
 13 BY MR. WENIK:
 14 Q So, Doctor, I've placed before you an
 15 email chain that I don't think you're a part of,
 16 actually. I don't think I see your name here.
 17 A No.
 18 Q Well, you're spoken about in the third
 19 person, but more so I wanted to ask you some
 20 questions about identifying people.
 21 So I guess I should ask you: Have you
 22 seen this before I just showed it to you? I
 23 assume not.
 24 A No.
 25 Q All right. Mark Blumenthal of the

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1 Daniel Fabricant, Ph.D.
 2 Q All right, and who is Tamara Ward?
 3 A She worked in the Office of Media
 4 Affairs.
 5 Q All right, and the talking points that
 6 are attached to this email chain, did she draft
 7 those or did she draft them in consultation with
 8 you?
 9 A There were people at OPA, and they
 10 consulted. We went back and forth. I'm sure the
 11 attorneys looked at them.
 12 Q All right, and were you satisfied with
 13 the adequacy of the talking points?
 14 A It was, it was fine. I mean it wasn't,
 15 it wasn't perfect. I mean we already had done
 16 some press on it. I think the key thing or the
 17 key message is in there, and that's usually what
 18 we focused on in interviews.
 19 Q Okay. I'm looking at the talking
 20 points, and it talks about the history of DMAA,
 21 and in the next to the last line, it talks about
 22 "it appears to have always had the same API in the
 23 same strength, 250 milligrams."
 24 Do you see that?
 25 A Mm-hmm, yes.

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1 Daniel Fabricant, Ph.D.
 2 American Botanical Council, do you know that
 3 gentleman?
 4 A I do.
 5 Q Who is Mark Blumenthal?
 6 A He started the American Botanical
 7 Council.
 8 Q Is this someone you had conversations
 9 or contact with while you were at the FDA?
 10 A I've known Mark since I was in graduate
 11 school.
 12 Q I take it the answer is yes?
 13 A Yes.
 14 Q Okay, and who is John Cardellina?
 15 A John Cardellina, I've known him for a
 16 while, too. He's a natural products researcher.
 17 Q Okay, and then we have a
 18 mark@herbalgram.org. Do you know who that is?
 19 A That's Mark Blumenthal.
 20 Q All right, and then we have a person
 21 listed here as James Neal-Kababick, Flora
 22 Research. I think we've already asked you about
 23 him.
 24 How about Anthony Almada? Who is that?
 25 Do you know anything about him?

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<p>1 Daniel Fabricant, Ph.D. 2 A Yes, I do. He's done research on 3 natural products and dietary supplements. 4 Q It looks like his email is a place 5 called "imaginutrition.com." Do you know what 6 that is? 7 A Imagine Nutrition, one of his companies, 8 yes. 9 Q Okay, and then we have a Stefan Gafner. 10 Who is Stefan? Do you know Stefan Gafner? 11 A Yes. 12 Q Who is he? 13 A He was a -- he used to work at Tom's of 14 Maine. He's a natural products chemist. 15 Q All right, and then there's someone 16 here, Tyler Smith at herbalgram.org. Do you know 17 who that is? 18 A He works for Mark Blumenthal. 19 Q All right. So Mark Blumenthal is 20 writing to Mahmoud ElSohly, who we've talked 21 about, talking about him, and the email is dated 22 April 15, 2013. "I appreciate seeing your 23 presentation this morning here at the Oxford ICSB 24 on your newest multi-center research on DMAA and 25 geranium leaf and oil."</p>	<p>1 Daniel Fabricant, Ph.D. 2 Do you see that? 3 A Mm-hmm, yes. 4 (Exhibit 37 was marked for 5 identification.) 6 BY MR. WENIK: 7 Q Doctor, I've placed before you as 8 Fabricant Exhibit 37 the agenda that I pointed out 9 from the archives page on the ICSB website back 10 for a conference that took place in April of 2013 11 that's referred to as Fabricant Exhibit 36. 12 Do you see that? 13 A Yes. 14 Q And it lists you, back in 2013, that you 15 were a session chair of one of the programs at 16 this conference; is that correct? 17 A Yes. 18 Q And what is the ICSB? 19 A International Conference on the Science 20 of Botanicals. 21 Q And what is your understanding of what 22 that -- is that associated with the University of 23 Mississippi and center? 24 A It has been for quite some time, yes. 25 Q All right, and I take it the conference</p>
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<p>1 Daniel Fabricant, Ph.D. 2 was held -- is this an annual conference? 3 A Yes. 4 Q And I take it this is held in Oxford, 5 Mississippi, near the university or on the 6 university campus? 7 A A little bit of both. 8 Q Okay, and so if we look at this agenda 9 that I've marked as Fabricant Exhibit 37, you're 10 listed as having been the session chair, and then 11 there's a description of a session by Dr. Mahmoud 12 ElSohly entitled "A Multicenter Study Showing the 13 Absence of DMAA in Pelargonium." 14 Do you see that? 15 A Yes. 16 Q All right. Do you recall whether you 17 attended that session that Dr. ElSohly gave? 18 A Yes. 19 Q And during that session, did Dr. ElSohly 20 mention, to your recollection -- and I know it's 21 three years later, but I would think you would 22 remember this if it happened. Did he mention that 23 he had found DMAA in geraniums at that session? 24 A I don't believe so, but again, like I 25 said, they published the paper. He definitely</p>	<p>1 Daniel Fabricant, Ph.D. 2 said that they didn't confirm the presence of it, 3 which is more important from where I was sitting. 4 Q All right. 5 (Exhibit 38 was marked for 6 identification.) 7 BY MR. WENIK: 8 Q So, Doctor, I placed before you a 9 document that I marked for identification as 10 Fabricant Exhibit 38, which I'll represent to you 11 is the slide presentation that Dr. ElSohly gave at 12 the ICSB conference in 2013. 13 A Okay. 14 Q And my first question to you is: What 15 is your understanding as to whether or not a slide 16 presentation like this -- what review, if any, 17 does it undergo? Is it like a poster presentation 18 where sometimes they peer-review these sort of 19 things, or what is your understanding? 20 A No, it's -- I mean this was a, a rapid 21 communication, if you will. It's not the same as 22 the peer-reviewed process, but it doesn't mean it 23 wasn't good work. It's just not the peer-review 24 process. 25 Q And did Dr. ElSohly share with you these</p>

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<p>1 Daniel Fabricant, Ph.D. 2 slides before he presented them at the ICSB 3 conference? 4 A No, but we got them after. 5 Q Do you mean the FDA got them after? 6 A Yes. 7 Q All right. So let me turn your 8 attention to -- unfortunately, the pages are not 9 numbered, but it's 11 pages from the end. 10 A 11 pages from the end? 11 Q I think you got it right there. 12 A Okay. 13 Q So we have a table there. 14 A Mm-hmm. 15 Q And one column lists various samples of 16 Pelargonium. 17 A Yes. 18 Q Another column gives you a specimen 19 number, and then the third column talks about 20 DMAA, and then it says "ND." 21 Do you see that? 22 A Yes. 23 Q Would you agree with me the "ND" stands 24 for "not detected"? 25 A I believe that's what it was in this</p>	<p>1 Daniel Fabricant, Ph.D. 2 context, but interestingly enough, he doesn't have 3 it notated, so I'll assume that's what it means. 4 Q All right. If we look back at the 5 article that I showed you as Fabricant Exhibit 25, 6 if you look at the third page in this article, 7 there's a table, and similar to the page we looked 8 at here, he has the specimen numbers in one 9 column, and in the final column he has "ND," and 10 he actually has a footnote here where he says "ND 11 means no detectable levels of DMAA." 12 Do you see that? 13 A Yes. 14 Q And would you agree with me that both in 15 the slides and in the article, the authors have 16 listed that DMAA was not detected in any of the 17 specimens that are listed here? 18 A That's what it appears to say. 19 (Exhibit 39 was marked for 20 identification.) 21 BY MR. WENIK: 22 Q Doctor, I've placed before you a series 23 of emails and attachments that I marked for 24 identification as Fabricant Exhibit 39. I'll ask 25 you to take a look at that for a little bit, and</p>
<p>Page 180</p> <p>1 Daniel Fabricant, Ph.D. 2 then I'll ask you some questions. 3 (Witness peruses document.) 4 BY MR. WENIK: 5 Q I've placed before you Fabricant Exhibit 6 39. I understand that you didn't author these 7 emails, but I want to ask you some questions 8 anyway. 9 So on the first page there's a reference 10 to using something called "the MRM method." What 11 would your understanding be of what the MRM method 12 stands for? As a chemist, what would your 13 understanding be of what that stands for? 14 A In this instance, I'm not -- I didn't 15 perform the analysis, so I don't know. 16 Q Okay. All right. 17 If we look back at Exhibit 25 and the 18 table that we have on page -- Table 1 of the 19 exhibit, which is at page 3. At the top of the 20 table it talks about Table 1, and it says, 21 "Pelargonium plant material and oil samples used 22 in the study and the results of their analysis for 23 DMAA," and then it goes on to talk about some of 24 the different centers or laboratories that studied 25 it, including the School of Pharmacy at Second</p>	<p>Page 181</p> <p>1 Daniel Fabricant, Ph.D. 2 Military Medical University in Shanghai, China, 3 and Shanghai Institute of Materia Medica. 4 A Yes. 5 Q Are you familiar with the Shanghai 6 Institute of Materia Medica? 7 A Inasmuch that they are partners with the 8 NCNPR. That's about the extent. 9 Q All right. Is it a nonprofit 10 institution, a for-profit institution, or -- 11 A As far as I understand, it's an 12 institution of traditional medicine in China. 13 Q Okay, and I'm looking at Fabricant 14 Exhibit 39. I'm looking at the Bates stamp page 15 2270 at the bottom. 16 A Okay. 17 Q And there's some chromatograms there, 18 correct? 19 A Yes. 20 Q And then it says in Figure 5 -- this is 21 entitled "Examination of DMAA in Pelargonium plant 22 material, Shanghai Institute of Materia Medica," 23 and then there are some chromatograms, and it says 24 at the bottom, "MRM chromatograms of some plant 25 samples. 1,3-dimethylamylamine was detected in S1</p>

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1 Daniel Fabricant, Ph.D.
 2 and S2. The isomer of 1,3-dimethylpentylamine was
 3 detected," and then it gives some sample numbers,
 4 13040, 13041, 13047, 13048 and 13049.
 5 Do you see that?
 6 A Okay.
 7 Q And if we look at the table in the chart
 8 for the corresponding sample numbers, the office
 9 wrote, contrary to what had been submitted to them
 10 by the Shanghai Materia Medica Institute, that
 11 DMAA was not detected, correct?
 12 MR. SCOTT: Object as to form. It
 13 assumes facts clearly not in evidence.
 14 You can answer if you can.
 15 THE WITNESS: Yeah, I mean this
 16 isn't my -- you know, in reading this, I mean
 17 Khan's pretty clear about 2 nanograms is
 18 under the detection limit, it says right
 19 here, so there's -- I mean there's not
 20 confirmation, so that's what matters.
 21 BY MR. WENIK:
 22 Q Did Khan or ElSohly ever share with you
 23 these documents from the Shanghai Institute of
 24 Materia Medica?
 25 A No, I don't have these documents, and I

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1 Daniel Fabricant, Ph.D.
 2 2 nanograms is under detection limit, and in the
 3 email it says that it was under 2 milligrams, it
 4 sounds like it's below detection limit. So I
 5 don't know that what they presented was different
 6 from that.
 7 Q If you look at --
 8 A It's not a confirmation either way,
 9 and -- yeah.
 10 Q If you look at the article, this one
 11 here, Fabricant Exhibit 25, so if you look at the
 12 fifth page.
 13 A Okay.
 14 Q There's tables 2, 3, 4 and 5.
 15 A Yes.
 16 Q And the authors of the study publishing
 17 the article, the limits of detection that were
 18 used by the Second Military Medical University of
 19 Shanghai china in these four tables; is that
 20 correct?
 21 A Yes, but that's different than this.
 22 Q Right. They don't include any
 23 information about the levels of detection used by
 24 the Shanghai Materia Medica, do they?
 25 MR. SCOTT: Read as much as you

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1 Daniel Fabricant, Ph.D.
 2 wouldn't remember anyway. That was these years
 3 ago.
 4 Q Do you know whether they shared that
 5 information with the FDA?
 6 A Again, I -- this is --
 7 MR. SCOTT: To the extent you know.
 8 THE WITNESS: No, I don't know.
 9 BY MR. WENIK:
 10 Q Would you consider it an act of academic
 11 dishonesty to publish results for a center that
 12 were different than what had been communicated to
 13 you by the laboratory?
 14 MR. SCOTT: Symptom.
 15 THE WITNESS: Yeah, I don't know
 16 that that's the case, so I can't speculate.
 17 BY MR. WENIK:
 18 Q And I take it that at the ICSB
 19 conference in 2013 when we looked at the
 20 PowerPoints and similarly said none detected,
 21 there was no mention of any of these documents
 22 either, were there?
 23 A You saw the same PowerPoints I did, so
 24 again this is -- you know, I don't know that what
 25 you're saying is a fact either. So if he's saying

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1 Daniel Fabricant, Ph.D.
 2 need to see if that's the case or not.
 3 THE WITNESS: I don't see it here.
 4 However, is there a supplemental?
 5 BY MR. WENIK:
 6 Q Not that I'm aware of.
 7 A "Additional supporting information will
 8 be found online version of these articles" --
 9 THE REPORTER: Can you slow down,
 10 please?
 11 THE WITNESS: Yeah. Do you have a
 12 supplemental?
 13 BY MR. WENIK:
 14 Q I do not.
 15 If ElSohly and Khan had fabricated and
 16 manipulated the results of their study, would that
 17 change your view as to the regulatory action for
 18 the FDA to take in regard to DMAA?
 19 MR. SCOTT: Object as to form.
 20 THE WITNESS: They didn't.
 21 BY MR. WENIK:
 22 Q How do you know they didn't?
 23 A Here is what I do know is you have it
 24 occurring in company-founded studies,
 25 company-paid-for studies in non-peer-reviewed

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1 Daniel Fabricant, Ph.D.
 2 journals that no one else has ever replicated and
 3 the type of work that would need to be done to
 4 show, one, that it's possible for the plant. I'm
 5 not aware of a biosynthetic pathway that does it.
 6 Furthermore, I'm not familiar with a biosynthetic
 7 pathway in nature that produces exactly four
 8 optical isomers in identical quantities again and
 9 again and again.
 10 There's I think ample findings, and the
 11 work of the government wasn't just dependent on
 12 the work Khan and ElSohly did. It was dependent
 13 on -- there's a litany of what's here and why the
 14 rendering was made by the agency that it doesn't
 15 fit into a dietary ingredient.
 16 So, you know, it's not appropriate for
 17 the space. It's not a dietary ingredient. It's
 18 something that was a drug that all of a sudden,
 19 almost 50 years after the fact of it being
 20 approved as a drug, somebody finds it in nature?
 21 That doesn't happen in the natural products world.
 22 Could it happen? Possibly, but it doesn't happen.
 23 So again, I think -- I don't see -- I
 24 guess we just have a difference of how we see it,
 25 Mr. Wenik.

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1 Daniel Fabricant, Ph.D.
 2 be subject to the provisions of regulations that
 3 require NDI?
 4 A It could. More than likely it would be
 5 required to show -- it would either have to have a
 6 full food additive petition or a full GRAS
 7 notification, more than likely.
 8 Q And if it had neither of those, would it
 9 be considered that products including it that are
 10 being sold as foods to be adulterated?
 11 MR. WENIK: Objection to form.
 12 THE WITNESS: Yes.
 13 BY MR. SCOTT:
 14 Q And to your knowledge, were either of
 15 the paths to NDI followed in relation to DMAA?
 16 A No.
 17 MR. SCOTT: No further questions.
 18 MR. WENIK: I have no redirect. I
 19 thank you for your courtesy.
 20 MR. SCOTT: He will read and sign.
 21 (Signature having not been waived,
 22 the deposition of DANIEL FABRICANT,
 23 Ph.D. was concluded at 2:41 p.m.)
 24
 25

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1 Daniel Fabricant, Ph.D.
 2 Q Fair enough.
 3 Did ElSohly ever communicate to you that
 4 Shanghai Institute of Materia Medica had detected
 5 DMAA in any amount in a geranium sample?
 6 A I don't recall.
 7 Q How about Dr. Khan?
 8 A I don't recall.
 9 MR. WENIK: I have nothing further.
 10 THE WITNESS: Okay.
 11 MR. SCOTT: I have just a couple.
 12 EXAMINATION BY COUNSEL FOR UNITED STATES
 13 BY MR. SCOTT:
 14 Q In a couple of instances, Mr. Wenik
 15 asked you about the burden that would be on FDA to
 16 ban a dietary ingredient.
 17 Do you recall that?
 18 A Yes.
 19 Q Did FDA conclude that DMAA was a dietary
 20 ingredient?
 21 A No. It concluded it was not. It
 22 concluded it was an unapproved food additive, and
 23 therefore it couldn't be banned as a dietary
 24 ingredient.
 25 Q As an unapproved food additive, would it

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1 Daniel Fabricant, Ph.D.
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 5
 6 ACKNOWLEDGEMENT OF WITNESS
 7 I, Daniel Fabricant, Ph.D., do
 8 hereby acknowledge that I have read and
 9 examined the foregoing testimony, and the
 10 same is a true, correct and complete
 11 transcription of the testimony given by me,
 12 and any corrections appear on the attached
 13 Errata sheet signed by me.
 14
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 16
 17 (DATE) (SIGNATURE)
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1 Daniel Fabricant, Ph.D.
 2 ERRATA SHEET
 3 DATE:
 4 WITNESS:
 5 CASE:
 6 PAGE LINE CORRECTION AND REASON
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1 Daniel Fabricant, Ph.D.
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 4
 5 CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC
 6 I, Laurie Donovan, Registered
 7 Professional Reporter, Certified Realtime
 8 Reporter, the officer before whom the
 9 foregoing deposition was taken, do hereby
 10 certify that the foregoing transcript is a
 11 true and correct record of the testimony
 12 given; that said testimony was taken by me
 13 stenographically and thereafter reduced to
 14 typewriting under my supervision; and that I
 15 am neither counsel for, related to, nor
 16 employed by any of the parties to this case
 17 and have no interest, financial or otherwise,
 18 in its outcome.
 19 IN WITNESS WHEREOF, I have hereunto
 20 set my hand and affixed my notarial seal this
 21 28th day of November, 2016.
 22 My commission expires: March 14th, 2021
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LAURIE DONOVAN
 NOTARY PUBLIC IN AND FOR
 THE DISTRICT OF COLUMBIA

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